ALTUS
DRUG DEVELOPMENT

Your Go-To Company for Value-Added Medicines

Experts in Value-Added Medicines

Based in the R&D
hub of Laval, Canada,
we design, develop and deliver
Value-Added Medicines.

We provide patients, prescribers, partners
and payers with cost-effective new products
in the growing CNS space.

Value-Added Medicines:
Why?

- Cost of in-house NCE development prohibitive to most companies globally
- In-licensing of NCE too expensive
- Pricing pressures making generic model uneconomic – race to the bottom

An alternative middle ground is required

An alternative middle ground

We breathe new life into proven and trusted drugs, creating **novel patent-protected, label-differentiated medicines** with new therapeutically beneficial features, unique positioning and premium pricing - at a fraction of the development cost of an NCE.

The 4P of VAM Selection

Altus' Criteria for VAM Development and In-Licensing

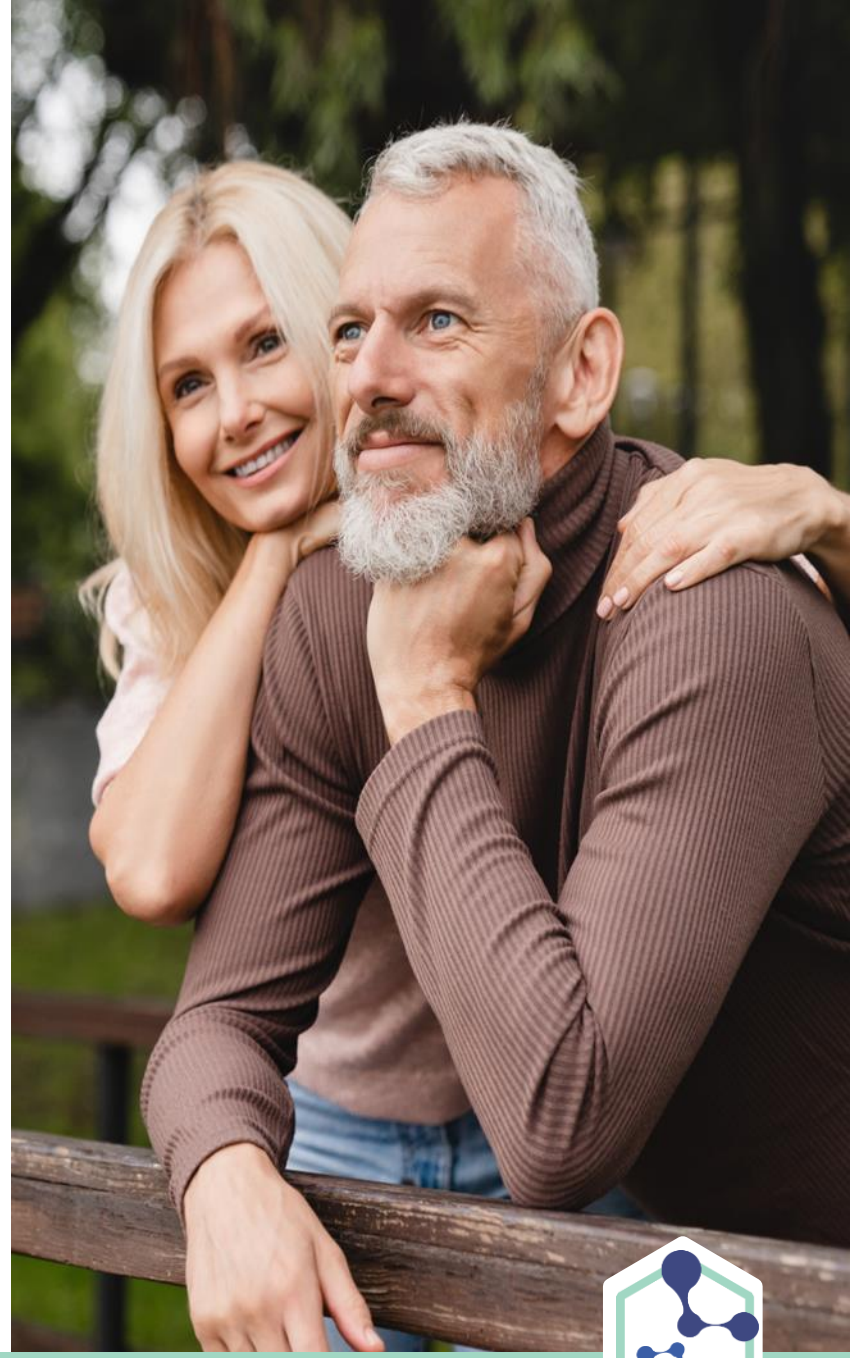
The 4Ps of VAM

The Altus Approach

To qualify as an Altus VAM candidate, opportunities must appeal to the key stake-holders

Patients: Must bring meaningful benefits to patients. Must result in new label claims

- Benefits must be clinically meaningful - not just improved convenience. Patients must **feel** the benefit
- Benefits must not greatly change patient habits and must be simple to explain to ensure compliance



The 4Ps of VAM

The Altus Approach

Prescribers: Must make all physicians' lives **easier** - not more difficult (from KOL to GP)

- VAM must be simple to use and simple to explain to and by physicians
- Clinical benefit must be valuable to prescriber as well as patient e.g. making prescribing easier
- Must not be cost-prohibitive (for public **or** private payers)

The 4Ps of VAM

The Altus Approach

Payers: Payers today will not support big, if any premiums. Value must come from capturing market share and expanding use post-approval (Ph IV strategies)

- Development costs and time-to-market must be minimized
- Manufacturing cost of goods must be minimized
- Product must be protected in the market – the **4th P!**

The 4thP of VAM: Patents

Exclusivity can only be guaranteed based on costly Ph III studies

Robust patents are essential to secure market share

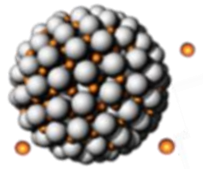
How We Do It – Our Technologies

Patented technologies to extend in-market protection over and above exclusivity periods

FlexiTab Tablets

Breakable extended-release tablets ideal for titration-sensitive drugs

MicroSpheres+

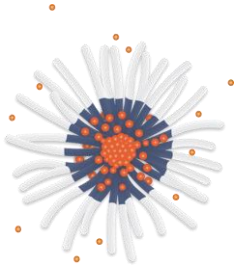


Versatile bioavailability-enhancing technology for targeted delivery, modified release, MR liquids and sprinkles

Flexitab ODT

Instant-release and MUPS extended release orally-disintegrating tablets

SmartCelle



COMING SOON : Dynamic smart micelles for parenteral and ocular delivery of insoluble drugs

Making Good Medications Better

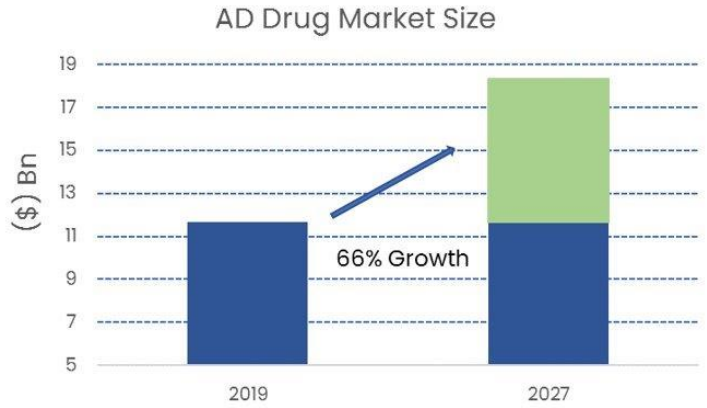
CNS CASE STUDIES

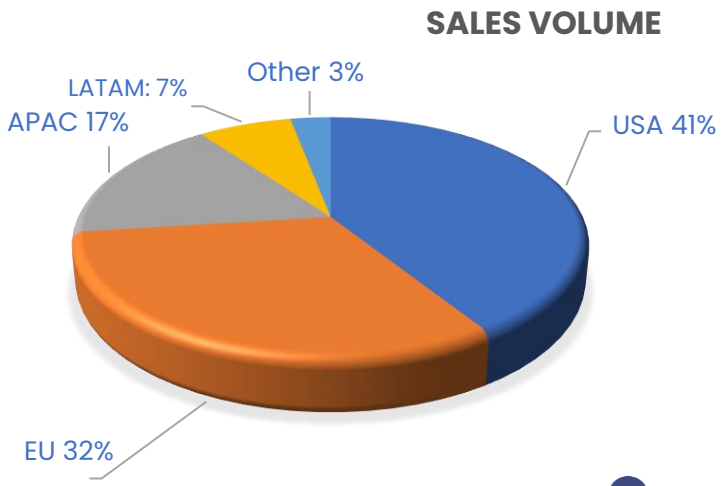
Depression


OVERWHELMED
CONFUSION
ANXIETY
NERVOUS
STRESS
FAILURE
FEAR
BREAKDOWN
PROBLEM
DISORDER
DEPRESSION
WITHDRAWAL
PANIC
MIND
FRUSTRATION
PRESSURE
OVERLOADED

Depression – A Sign of the Times

- 1 in 5 adults worldwide (ca. 300,000,000) suffer from depression at any one time; 50% more women than men
- The incidence of depression is increasing as populations age and post-pandemic. As a consequence:
  - The global market for antidepressants ca. $15Bn[1,2] in 2020
  - Now growing at ca. 5-8% to reach $26Bn by 2030.
  - Market dominated by USA/EU but APAC and LATAM growing rapidly as more private payers emerge and prescribing becomes less stigmatized





Antidepressants
The challenge

- **Efficacy** is not seen with most ADs for at least a month
- **Side-effects** occur immediately after starting AD therapy
- **Switching** AD medications due to side-effects is common: most patients switch AD's 3 times
- **No new treatments** for major depression have entered the market in recent years

AD - Antidepressant

Trazodone

An excellent drug poorly delivered

1.

Trazodone is an atypical class of anti-depressant that was originally developed in an immediate release oral form

2.

As a molecule it has a superior side effect profile vs other treatments with reduced insomnia, weight gain & sexual side effects

3.

It has also been clinically proven to have a faster onset of action vs standard of care treatments

4.

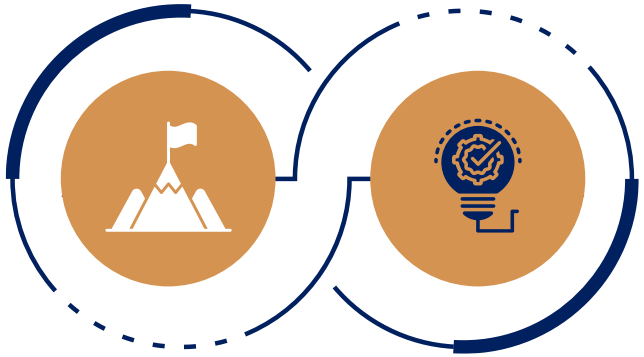
However, the original IR form of Trazodone causes high levels of sedation and somnolence due to its rapid onset of action

5.

Trazodone has therefore been primarily prescribed as a night-time sedative to be taken in combination with other anti-depressants

Challenge

To deliver all the clinically proven benefits of Trazodone in a convenient once-a-day format without the unwanted day time sleepiness



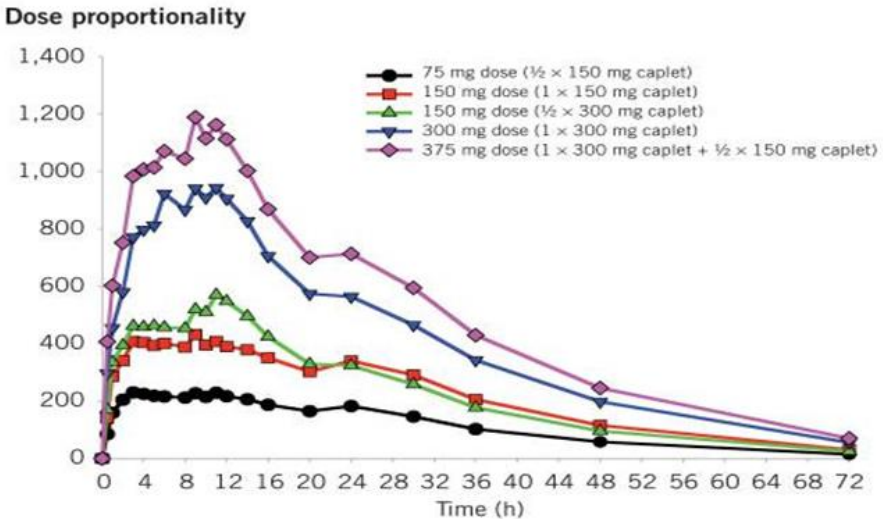
Solution

TrazoFlex – A once-a-day formulation of Trazodone in a proprietary breakable extended release format

TrazoFlex

A Value-Added AD

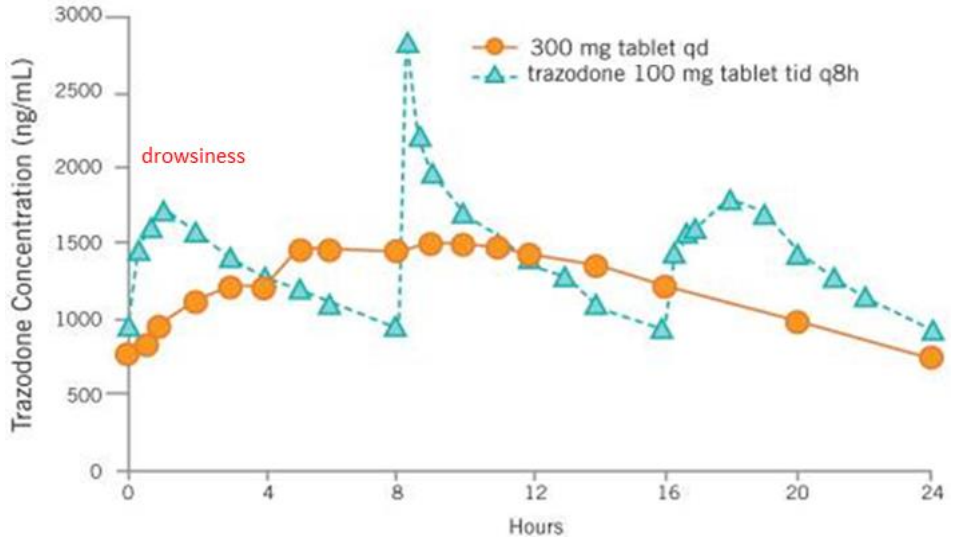
- Once-daily **TrazoFlex** tablets taken at bedtime to overcome daytime somnolence
- Breakable 300mg and 150mg tablets generate five doses, enabling **titration from just two tablets.**
- Precision Medicine approach **improves patient experience** and avoids switching common with ADs



TrazoFlex
Additional Benefits

In clinical studies, TrazoFlex tablets

- **Did not cause weight gain** or sexual side-effects of SSRIs
- **Reduced daytime somnolence** of the most frequently-used IR trazodone tablets by 90%
- **Achieved clinically significant improvements** in mood within the first week of treatment
- **Improved sleep architecture** with benefits on mood.
- Were **well-tolerated**



*AD - Antidepressant

TrazoFlex

Product Development

- TrazoFlex tablets are bio-equivalent to products approved and on sale in the USA, EU and Latin America for **cost-effective commercialization**
- **Breakable tablet features** can be included in label
- TrazoFlex tablets are **protected by patents to 2038**

Development status:

TrazoFlex is ready for supply

*AD - Antidepressant

Desvenlafaxine

An SNRI with more to give

1. Desvenlafaxine (Pristiq) is an SNRI-type antidepressant only available in XR form

2. As a molecule, it is therapeutically equivalent to venlafaxine with serotonin and noradrenaline enhancing properties

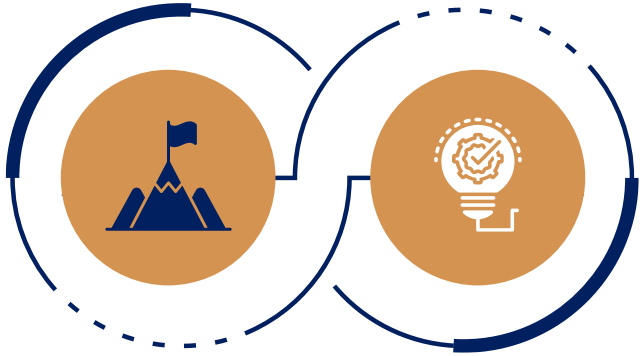
3. The efficacy benefits of Double Reuptake Inhibition are only achieved at doses above 200mg

4. However, dose limiting side-effects occur with increasing doses

5. Desvenlafaxine use has therefore been limited due to the inability to get to higher doses with good tolerability

Challenge

To deliver all the double reuptake inhibition benefits of Desvenlafaxine and expand the utility of desvenlafaxine to match/exceed venlafaxine



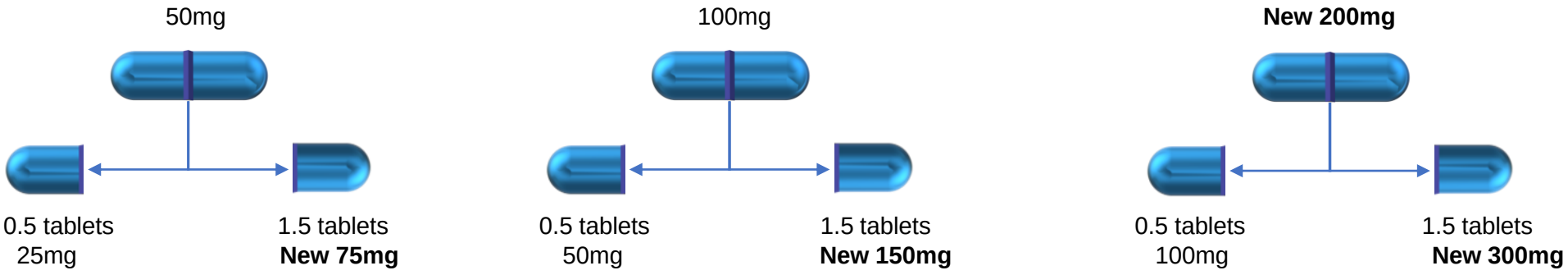
Solution

DeslaFlex – A once-a-day formulation of Desvenlafaxine in a proprietary breakable extended-release format with new dosing options

DeslaFlex

A patient-focused improvement

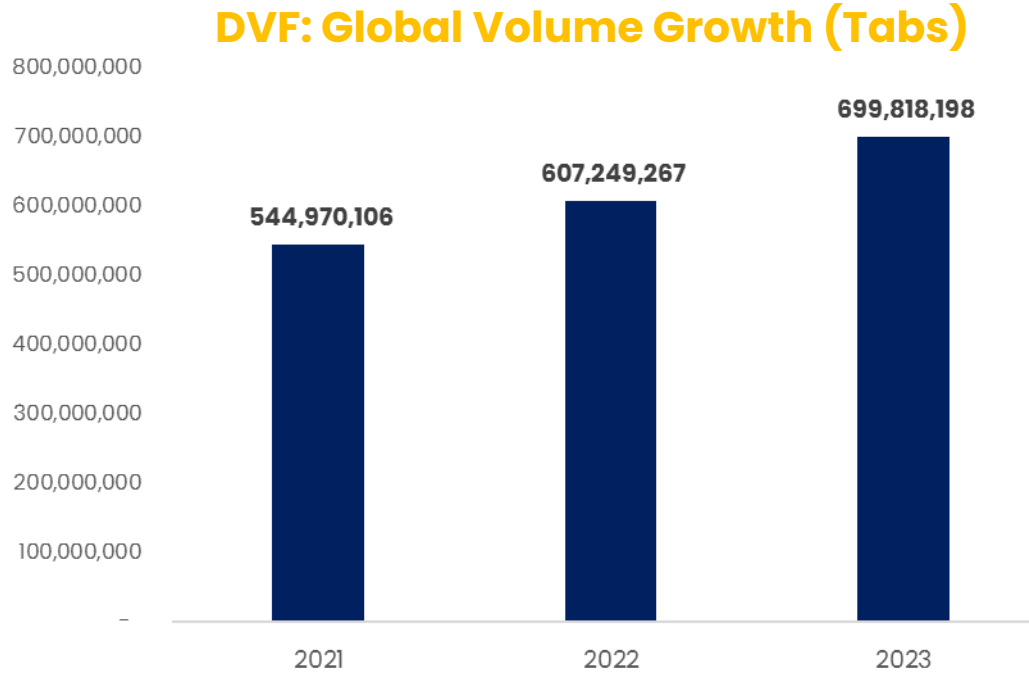
- Breakable once-daily tablet formulations of desvenlafaxine in 50mg, 100mg and 200mg strengths
- Breaking DeslaFlex tablets generates **7 multiple-dose proportional strengths** – with three brand new dosing options - to aid titration and tapering
- Enables more effective dosing at higher strengths without increasing the number of strengths on the market.
- Provide an opportunity to treat more patients more safely and expand utility of desvenlafaxine vs venlafaxine
- Novel dosage strengths offer opportunities for premium pricing based on new label claims



DeslaFlex

A Better Range of Strengths

- Simplified dosing ensures naïve patients get the right dose for them
- Dosing flexibility for long term patients means they get the lowest beneficial dose
- Low-step titration to higher strengths while managing treatment failures to minimize switching due to AE's



*AD - Antidepressant

DeslaFlex

Product development

Planned approval through dose proportional bioequivalence to Pristiq via 505(b)(2) pathway

- Timeline to filing: within 24 months
- Intellectual Property: Formulation based on Flexitab technology covered by patents up to 2038
- Additional formulation patents covering new 200mg strength and breakability feature in label
- Cost effective manufacturing partnerships in place to enable a lean supply chain set up

Development status:

Formulation development matching Pristiq successfully completed

*AD - Antidepressant

Neuropathic and Moderate to Severe Pain

Chronic Pain

Results of a 19,000-respondent study conducted in 2020 [1];

Pain remains a global issue which cannot be ignored

1/3
of the world's population is in pain

93%
suffered significant pain in the last year (+2% vs 2018)

1 in 5
sufferers is under 30

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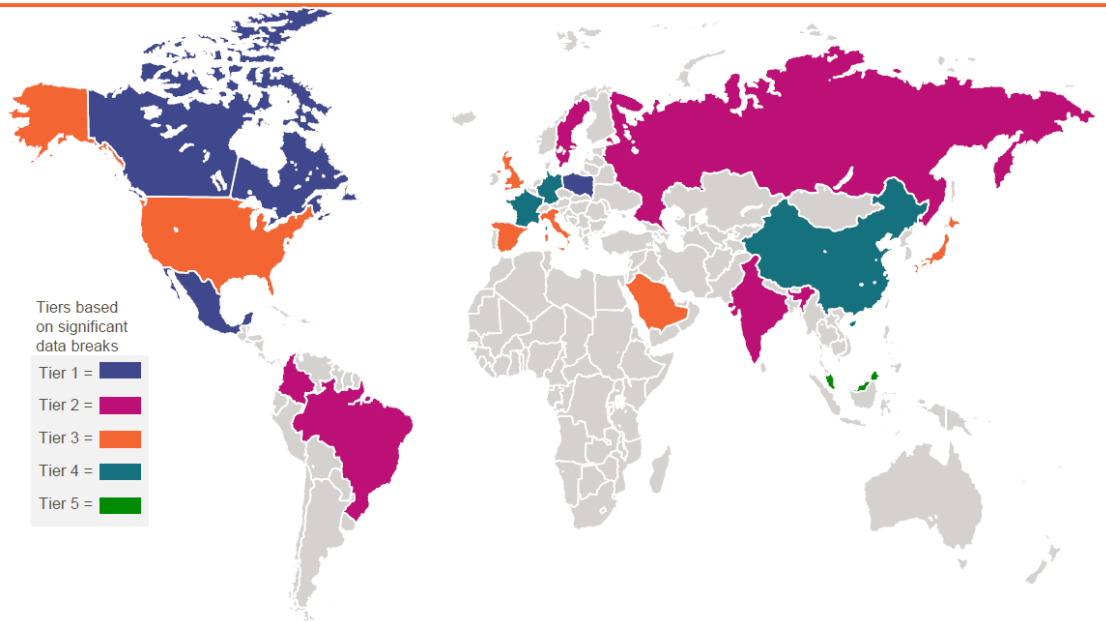
Chronic Pain

Results of a 19,000-respondent study conducted in 2020 [1;]

2 billion individuals suffered reportable pain in the previous year in the 19 countries studied



Poland	99%
Mexico	98%
Canada	98%
Brazil	97%
Russia	97%
Colombia	97%
India	96%
Italy	96%
Australia	96%
Sweden	96%
USA	94%
Japan	94%
UK	94%
KSA	94%
Spain	93%
France	92%
Germany	91%
China	90%
Malaysia	86%

Managing Pain

The Challenge

73%

wish more could be done to help manage their pain

*".we struggle to find **effective** and **non-addictive** solutions…"*

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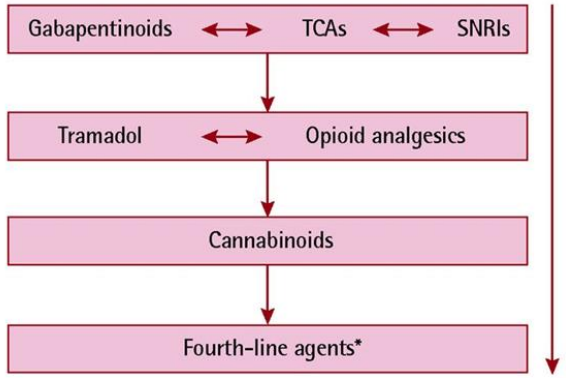
Treating Neuropathic Pain
An overview

Gabapentinoids (gabapentin and pregabalin) are most frequently used first line treatments.

Treatment guidelines neuropathic pain Canadian College of Family Physicians



- Neuropathic Pain market is large with growth in all regions expected to grow significantly due to an aging population and increasing incidence of obesity/diabetes leading to DPN.
- Global neuropathic pain market is expected to account for $10Bn by 2030 with CAGR ca. 5%-8%

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Pregabalin

A blockbuster with room for improvement

1. Pregabalin is a gabapentinoid originally developed in IR format with a CR format now available in the US.

2. Unlike predecessor Gabapentin, it is absorbed rapidly and more completely throughout the small intestine enabling prolonged release forms.

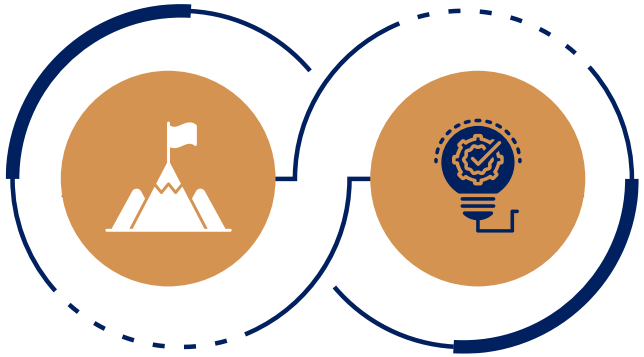
3. A large number of strengths is required to titrate patients with neuropathic pain, especially in renal failure (diabetic) cases

4. However, Lyrica CR is only available in three strengths, which does not facilitate titration

5. The CR version of pregabalin is therefore limited to the US and of limited use

Challenge

To deliver all the benefits of neuropathic pain relief in doses that are patient-friendly and facilitate recommended titration schedules



Solution

NeuroFlex - a once-daily controlled release breakable formulation of pregabalin offering new dosing options

NeuroFlex

Once-daily Pregabalin CR tablets

NeuroFlex offers the dosing versatility of blockbuster Lyrica IR capsules with the convenience and compliance benefits of a once daily tablet

- Scored tablets can be broken to create seven different doses - **with three new dosing options**
- NeuroFlex tablets provide 24H relief – at doses patients need

41.25mg 82.5 mg 123.75mg I 82.5mg 165mg 247.5mg I 165mg, 330mg, 495mg 660mg

NeuroFlex

Once-daily Pregabalin CR tablets

The convenience of a once daily tablet. The flexibility of an IR capsule.

- Nighttime dosing helps eliminate breakthrough pain and seizures while enhancing compliance
- Multiple strengths allows greater ability to manage complex conditions
- Novel low and intermediate dosage strengths ensure patients receive only the dose they need, and no more
- Flexible dosing options from low dose (41.25mg) to high dose (495mg) allow effective treatment of a wide range of patients with different conditions and more titration options to ensure tolerability
- Three doses from one prescription allow dose adjustments from a single script

NeuroFlex

Global Commercialization Strategy

Altus intends to obtain approval of NeuroFlex tablets in the USA by demonstrating bio-equivalence to Lyrica CR tablets via the 505(b)(2) pathway

- The new label for NeuroFlex tablets will highlight breakability
- Development will be efficient, cost-effective and milestone-driven with multiple go/no go to control costs

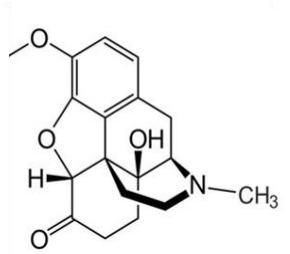
Altus is seeking co-development partners to join a consortium and share development costs in return for exclusive territorial rights

This model offers additional cost control benefits and risk sharing

Manufacturing can be transferred to a partner's facility or centralized via Altus' CMO partner.

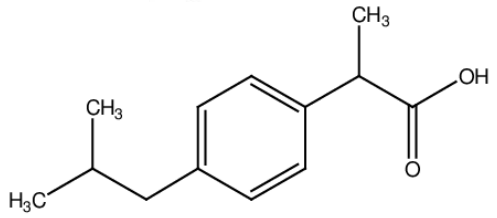
Treating Moderate to Severe Pain
The Challenges

Opioids can no longer be prescribed due to abuse and addiction and consequent prescribing/supply restrictions



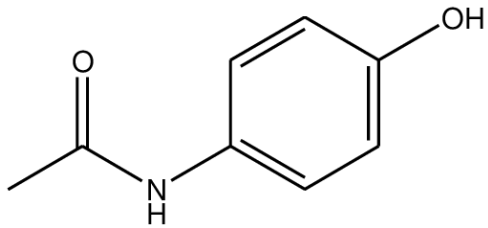
Oxycodone

NSAIDS are ideal for mild short-term pain - but cause serious gastrointestinal effects over longer periods



Ibuprofen

Paracetamol has no gastrointestinal side effects - but risk of hepatoxicity limits dosing for moderate to severe pain



Paracetamol

How can we treat Moderate to Severe Pain for billions of patients worldwide *without High-Strength Opioids*?

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Paracetamol + Tramadol

A fixed-dose combination

1. Tramadol/Paracetamol is a fixed-dose combination originally developed in an IR format

2. The unique MoA of Paracetamol and Tramadol synergize to generate multi-modal analgesia

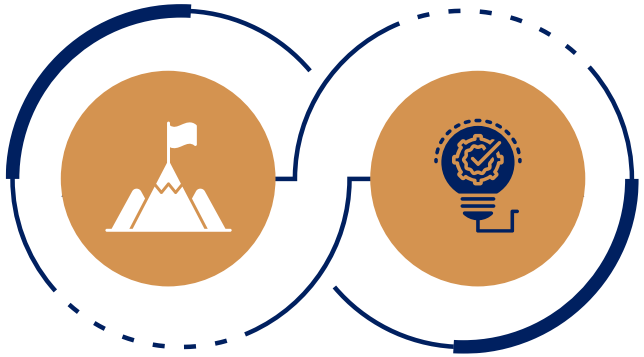
3. It has an increased analgesic effect vs. single agents without increased dose - opioid and APAP sparing

4. However, the 37.5mg/325mg IR tablets must be taken 4-6 times per day which is not patient friendly

5. The original IR dosing options increase the risk of non-compliance, poor sleep and break-through pain

Challenge

To deliver all the analgesic properties of the IR version in patient-centered dosing intervals to avoid breakthrough pain.



Solution

AcetraFlex - A 12hr duration extended release fixed-dose tablet formulation of Paracetamol/Tramadol

Phase III Studies
Major Outcomes

- **Superior analgesic efficacy of AcetraFlex demonstrated** versus placebo (SPID50)
- **Greater pain relief for AcetraFlex** vs placebo (TOTPAR50)
  60% reduction in pain intensity during the study
- **Onset of Pain Relief by 30 mins post dosing** – Paracetamol mediated effect
- **12hr Efficacy** – Only 13% of patients required re-medication within the dosing periods
- **Safety: Treatment well tolerated** – No serious AE's related to treatment

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AcetraFlex
Approval and Licensing

- **Product Approved in Eight EU Countries** – Czech Republic, Iceland, Ireland, Poland, Portugal, Slovakia, Slovenia and Spain via European Union Decentralized Procedure
- **Licensed to Major EU Pain Specialty Company**
- **Launch in EU Delayed** due to PRAC decision on extended-release paracetamol products
- **PRAC decision now overcome**; initial commercialization in Spain.

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AcetraFlex

Global Commercialization Strategy

Altus and its European Partner are seeking

- **Licensees in all major territories** - Exclusive rights for the product including all improvements (e.g. breakable tablet).

- **General Terms**
  - Upfront licensee fee.
  - Regulatory milestones
  - Royalty on Net Sales

Finished product supplied by Altus/Partner.

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Tramadol

Making step II safer

1.

Tramadol hydrochloride is a mixed function analgesic with both opioid receptor and serotonin/noradrenaline reuptake activity.

2.

Although tramadol is not a true opioid narcotic, it has been associated with overdose deaths and frequent misuse and abuse

3.

As a consequence tramadol is now subject to scheduling and other controls in both N. America and Europe

4.

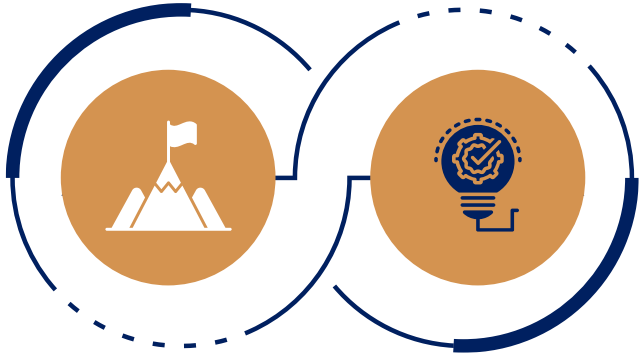
Formulations which mitigate the risk of inadvertent overdose may therefore be considered valuable in many jurisdictions.

5.

The ability to offer flexible dosing options with smoother titration can increase the appeal of tramadol

Challenge

To deliver all of the analgesic properties of Tramadol with more and better dosing options to mitigate the risk of overdose and abuse



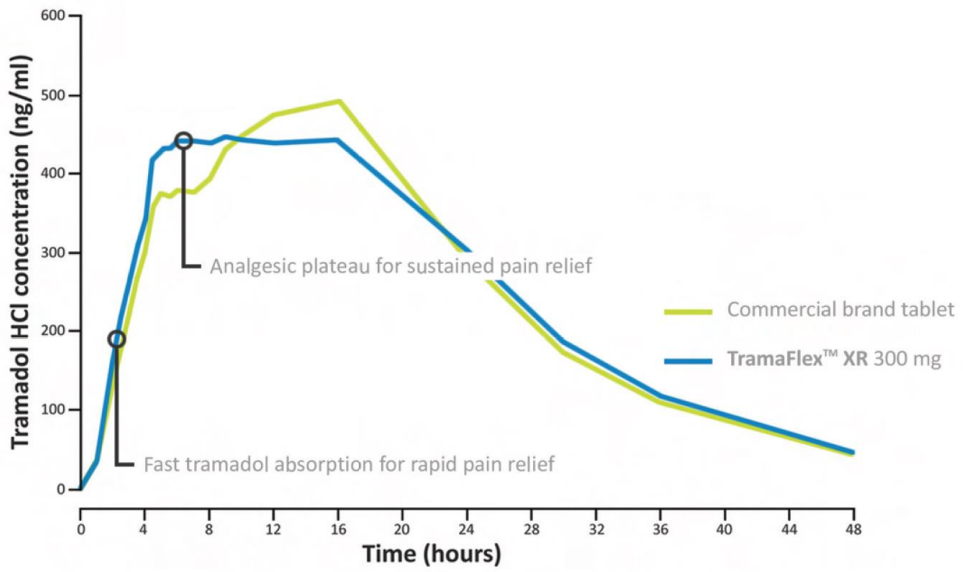
Solution

TramaFlex - a breakable controlled release tablet formulation of tramadol in a safer to use format with improved dosing options

TramaFlex by Altus
A Safer-to-use Step II Opioid

TramaFlex are fast-acting once-daily tramadol tablets designed to mitigate risks associated with opioid formulations

- Scored tablets use Altus' Flexitab platform to create six different dosage strengths from just three breakable tablets
- Broken tablet segments retain CR properties even when split



TramaFlex Tablets

Opportunity:

- Breakable Once-Daily Tramadol Tablets for Severe Pain.

  Bio-equivalent to leading non-breakable brands.

Benefits:

- Breakable 100mg, 200mg and 300mg tablets generate 8 different tablet strengths providing;
- New 50mg starting dose for lower body weight/frail patients
- Novel intermediate 150mg and 250mg doses
- Low step-increase dosing in 50mg increments
- Safer to Use design – no dose dumping when broken or in alcohol
- Rapid onset time and rise to steady state.

Bipolar and Schizophrenia

Quetiapine

A different drug at different strengths

1.

Quetiapine is a well-tolerated highly effective second generation anti-psychotic drug (SGA) available in IR and XR format

2.

As a molecule it is better tolerated and lacks the metabolic and extrapyramidal side effects of other SGAs.

3.

Quetiapine is "a different drug at different strengths" and as such is indicated for a wide range of psychiatric conditions

4.

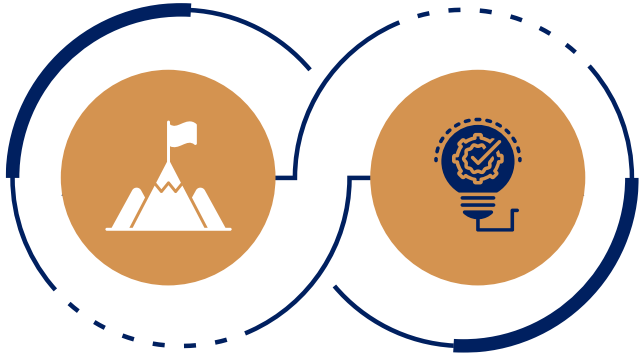
Starting doses are low, target doses are high and titration periods are short, requiring multiple strengths for a poorly compliant population.

5.

Simplified yet novel dosing options are required to serve these patients better and find the right dose for them.

Challenge

To deliver all the benefits of an SGA in multiple low doses and flexible higher doses from a minimum number of prescriptions.



Solution

QuetiaFlex - a once-daily breakable controlled release formulation of quetiapine providing maximum strengths in a minimum number of tablets

QuetiaFlex

Simpler prescribing for complex conditions

- Breakable QuetiaFlex QD tablets cover the range of strengths needed to treat patients with varying symptoms
- 3 flexible-strength tablets provide multiple low doses, simple rapid titration and flexible, high-dose adjustments from a minimum number of prescriptions.
- Flexible and once-daily dosing simplifies prescribing and can improve the lives of many patients with complex conditions

QuetiaFlex
Product Development

Altus intends to obtain approval of QuetiaFlex tablets by demonstrating bio-equivalence to Seroquel XR tablets

- The new label for QuetiaFlex tablets will highlight breakability
- Development will be efficient, cost-effective and milestone-driven

Altus is seeking co-development partners to join a consortium and share development costs/risks in return for exclusive territorial rights

Manufacturing can be transferred to a partner's facility or centralized via Altus' CMO partner.

Development status: QuetiaFlex is in product concept/TPP stage

Additional Concepts Under Development

Altus is seeking co-development partners for these breakable extended-release tablet concepts.

Drug Substance	Brand Reference	Indication	Value Added	Approval Route
Lamotrigine	Lamictal XR	Epilepsy	'start low go slow' to avoid seizures and minimize adverse events.	$505_{(b)(2)}$ $10_{(3)}$
Levetiracetam	Keppra XR	Epilepsy	'start low go slow' to avoid seizures and minimize adverse events and minimize dose	
Levetiracetam related molecule	Not disclosed	Epilepsy	Not disclosed	Not disclosed
Carbidopa/ Levodopa	Sinemet	Parkinson's disease	Simplified rapid dose adjustment	$505_{(b)(2)}$ $10_{(3)}$ (Complex generic)
Bupropion	Wellbutrin	Depression/s moking cessation	Simplified titration, precision dosing, improved tolerability and dose elevation	$505_{(b)(2}$

Patent Coverage

- **EU** - EP3694557B1 (multiple validations)
- **USA** - US11058773B2
- **UK** - GB2567493B25
- **Canada** - CA3034722C

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Our Business Model
General Structure

- Exclusive Co-Development and Licensing Agreement (CD&LA) under the Altus IP
- Initial VAM Development In-house at Altus
- Proof of Concept Studies (In vitro or in human)
- Technology Transfer to Partner Facility, Partner CDMO or Altus CDMO
- Process Scaling and Submission
- Finished Product Supply from Altus CDMO or Partner CDMO/Facility

.

Our Business Model

CD&LA General Structure

- Licensing Fee (Territory Dependent)
- Pass Through Development Fees (New Products Only)
- Development Success Milestones
- Royalty (or Equivalent) on Net Sales
- Sales Success Milestones

Our Business Model

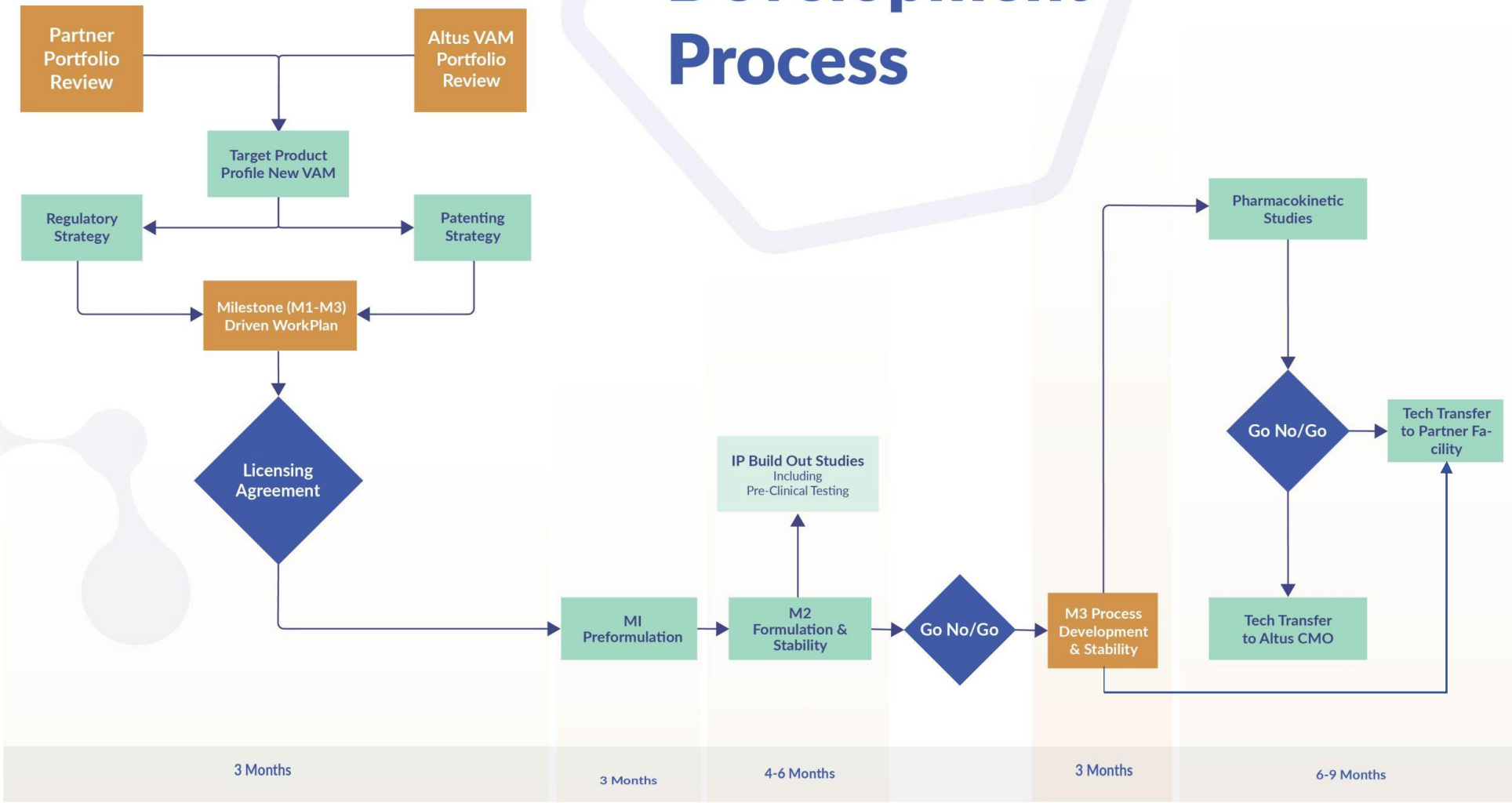
Two Options for Value-Added Medicine Projects

Altus Selected Projects: Value Added Medicines conceived and partially/fully developed by Altus meeting target product profile ready to;

- Supply to partner (e.g. TrazoFlex)
- Transfer to partner site

New Projects: Value Added Medicines conceived by the partner or Altus and co-developed by Altus and a partner

Our Drug Development Process



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