A legacy of success

- Decades of expertise
- Proprietary capabilities
- Global presence
- Continuous improvement to adapt and identify new obstacles to meet evolving market demands
- Complete in-house end-to-end capability with R&D and regulatory affairs team with global expertise
- Turnkey regulatory and clinical support
- Proud to be leading partners across Branded, Specialty, Generic, Veterinarian, and OTC segments

Transforming today’s medicine

- Focused on creating dosage form solutions for patients left behind
- Overcoming oral delivery challenges with proprietary product solutions
  - Taste Masking and ODTs
  - Customized Drug Release
  - Bioavailability Enhancement
- +30 years of expertise
- +40 products developed & manufactured
- Sold in >100 countries
Proprietary product solutions for patients with unique needs

- Differentiated delivery systems
  - Taste Masking and ODTs
  - Customized Drug Release
  - Bioavailability Enhancement
- High dose, IR, and/or customized release
- Drug formulations exhibiting unique release profiles can be combined in a single dosage form
- Patient-friendly, ideal for those who experience difficulty swallowing regular capsules and tablets

Customized drug release profiles

- Proprietary delivery systems overcome formulation challenges
- Optimize efficacy, safety, and dosing frequency
- Unique release profiles can be combined in a single dosage form
- Improve onset of action, variability of absorption between patients, and food effects variation
- Optimize therapeutic performance and increase patient acceptability
Research and Development

- Integrated R&D validated through to commercial manufacturing
- Full-service capabilities for even the most complex product creation
- In-house regulatory affairs team with proven global track record
- Flexible business model customized to fit your program

Manufacturing

- Experts in scale up from product development through commercial scale
- Global expertise with manufacturing facilities in the United States and Europe
- Approved for controlled substances (US)
- Tech Transfer
OUR FACILITIES

A GLOBAL FOOTPRINT THAT ENSURES THE SECURITY OF YOUR SUPPLY

Four development & manufacturing sites in the US and Europe
- Pharmaceutical Development and Manufacturing
  » VANDALIA, OHIO
- Precision Particle Fabrication
  » LENEXA, KANSAS
- Manufacturing Solid Oral Dosage
  » S. GIULIANO (MILAN), ITALY
- Manufacturing, Pancreatic Enzyme Center of Excellence
- Solid Oral Dosage
  » PESSANO (MILAN), ITALY

Our exclusive technologies and processes lead the way
- Increase productivity, manufacture complex products, and extend product lifecycles through our global R&D facilities
- >300 patents adding valuable IP to commercialized and developing products
- Our specialized delivery systems improve drug formulations and increase product impact

A GLOBAL FOOTPRINT THAT ENSURES THE SECURITY OF YOUR SUPPLY
Proven expertise in regulatory and quality
- Substantial global experience in all aspects of regulatory strategies required for NDA filing (including 505(b)(2)) and ANDA filings
- Expertise to file both European and US submissions
- Support for a complete filing or for CMC section filing, depending on need
- Support in maintaining approved submissions globally
- Harmonized quality system certified and periodically verified by the major regulatory bodies such as FDA, EMEA, ANVISA and audited by more than 15 customers per year across the sites.

Strict adherence to cGMP regulations
- Experts in international protocol and standards
- Outstanding environmental credentials
- Compliant handling of controlled substances and solvents

Full-service clinical support for complex product creation
- Full-service capabilities for even the most complex product creation
- The resources to engage in full-scale clinical product development
- Understanding of current regulatory, scientific and market access challenges
- Regulatory support at early and late stage product development
  » Pre-IND FDA meeting support
  » IND filing to Pre-NDA support
  » Management of NDA submissions
- Strategic and tactical consulting
- Clinical support through the entire product development process
OUTLICENSING OPPORTUNITIES

Diverse portfolio with global availability
- License our products in territories around the world through our global R&D facilities
- Our technologies include taste-masking, customized release, and bioavailability enhancement in diverse platforms
  - Extended Release Capsules
  - Extended Release Tablets
  - Taste Masked
  - Orally Disintegrating Tablets
  - Sachet
  - Liquid-to-Solid Suspension
  - Targeted Release

Rx and OTC products available across specialized and diverse therapeutic categories
- Cardiovascular
- Allergy/Sleep Aid
- Pain
- Gastrointestinal
- Respiratory
- Nutrition
- Veterinary
- Central Nervous System

A PROVEN TRACK RECORD WITH OVER 40 PRODUCTS FOR BLUE-CHIP CUSTOMERS IN MORE THAN 100 COUNTRIES
Parvulet addresses multiple challenges

- Ideal for patients with swallowing difficulties
  - Dysphagic patients
  - Mucositis patients
  - Pediatric & geriatric populations
- Allows for high drug loading
- Accurate dosing with every treatment
- Improves patient adherence
- Texture is easy to swallow
  - Masked for taste and smell

Parvulet is a patient-friendly format

Studies show 60-79% of the geriatric population and 25-45% of the pediatric will experience difficulty in swallowing.

Oral solid dosage form with final texture similar to that of apple sauce:
- Easily administered in 30 seconds
- Swallowing aid built into formulation
- Mimics natural swallowing mechanism with no choking hazards

Parvulet provides the perfect solution for patients who have difficulty swallowing.
AdvaTab® Advanced ODT technology
- Composed of finely micronized particles rapidly dispersing into a smooth, viscous suspension
- An easy-to-take dosage solution:
  » Masks bitter drug taste
  » Rapidly dissolves in the mouth without water
- Easy ingestion for pediatric, geriatric and dysphagic patients
- AdvaTab® tablets have been proven bioequivalent to immediate or sustained release formulations

Patented formulations and manufacturing process
- AdvaTab® incorporate uniformly dispersed, coated drug particles in a low-moisture, rapidly disintegrating matrix
- Formulated for acceptable taste, a disintegration time <30 seconds
- Suitable for push-through blister packs and multiple-packing configurations
- Up to 500 mg drug-loading capability

Micrographs of Formulation Stages

AdvaTab® with embedded Microcaps Technology

COMBINE ADVATAB WITH THESE ADARE TECHNOLOGIES FOR IMMEDIATE RELEASE OR CONTROLLED RELEASE OPTIONS

API Granule (Irregular Shape)
Microcaps API (Complete & Uniform Taste-masking)
AdvaTab ODT (Final Dosage Form)

CUSTOMIZED RELEASE
Diffucaps® | Microcaps®
Immediate Pulse
- Adjustable dosage strength and dissolution profile to achieve the desired in vivo pharmacokinetic profile
- Available as a capsule, orally disintegrating tablet, rapidly disintegrating tablet, or as a sprinkle
- Enhances drug solubility in sections of the gastrointestinal tract through combined use with other Adare technologies
- Reduces gastric mucosal irritation and food effect

Timed Pulsatile
- Multiparticulate system with release-controlling polymers
  - One or more functional polymer membranes are applied to a drug core resulting in a small, multi-layered bead
  - Solubility-modulation technology can be used to create an optimal pH
  - Organic acid layer is placed underneath the drug layer, while the alkaline buffer is placed over the drug layer
  - Coatings ensure that the individual layers are not depleted until release of the drug is complete

Timed Sustained
- Examples of Release Profiles
- Immediate Pulse
- Timed Pulsatile
- Timed Sustained

Diffucaps controls drug delivery and optimizes release profiles
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Microcaps taste masking and pore-former technology

The drug particles are coated using a combination of coacervation (phase separation) and spray coating to build polymeric membranes of varying porosity and thickness. The final dosage forms can be produced in:

- Powders
- Dry syrups
- Orally disintegrating tablets

The pore-former rapidly dissolves in the stomach for fast drug release, enhancing the probability of achieving bioequivalence to an immediate release (IR) reference listed drug (RLD).

Precisely and uniformly coated

- Individual drug particles deliver a smooth, pleasant mouthfeel, with no aftertaste
- (ODTs) in dosage strengths up to 500 mg
- Rapidly disintegrating tablets (RDTs) in higher-dosage strengths up to 1500 mg
- Sprinkles, dry sachets, and stick packs, chewable tablets
- Powder for extemporaneous suspensions
MMTS™ Minitabs provide the flexibility of multiparticulate dosage forms

- Flexible dose delivery
  - capsules
  - sachets
  - sprinkles
- Allows for a wide range of customized release profiles within a single capsule
- Precise delivery at lower dosage strengths through a range of tablet sizes
- Wide range of customized release profiles within a single capsule allows for titration of a broader range of dosages

Multiparticulate system with release-controlling polymers

- Functional membranes are applied to 1.0-2.0 mm cylindrical tablets to control release rates
- The small size facilitates the development of products that can offer multiple drugs or varying release profiles within a single capsule
- High drug-loading capability with the possibility to combine with a high-density formulation for high-strength formulations
Optimum® technology overcomes many of the inefficiencies and deficits of traditional techniques. Optimum® offers a wide range of modified release options using flexible format powders. It can match an extended release tablet’s performance in a suspension format. And with Optimum®, you don’t have to sacrifice taste to achieve a dispersed solid oral dosage form.

Optimum® delivers on the promise of precision microparticles at a previously unachievable scale

- Particle sizes down to 75 μm with Span values as low as 0.40
- Uses a nitrogen “carrier” stream
- Analogous to spray congealing
- No drying step or coating required
- Compatible with waxes, lipids, stearates, and gelatins
- Good for oral small molecules, nutraceuticals, agricultural applications, flavorings, and heat stable molecules
Stratµm™ offers controlled and pulse release options in an injectable form

Controlled Release
Stratµm™ technology titrates drug release kinetics to enable novel injectable drug delivery products. We create uniform, monodisperse microspheres using our technology. Our depots allow for discrete control over release rate, including linear kinetics, offering sustained release for any desired length of time. This application is particularly useful for pharmaceuticals for which compliance is critical, such as contraception, antipsychotic, addiction and bacterial resistance medications.

Pulse Release
The Stratµm™ technology revolutionizes injectable pharmaceuticals with delayed release of active pharmaceutical ingredients for true pulse release. We tuned the composition of the shell to release the active after 30 days. Stratµm™ is particularly useful to improve patient compliance by reducing the number of injections (i.e. vaccines or ocular therapies). It also enables previously unattainable dosing regimens and pharmacokinetics.

Stratµm™ microparticles open up a whole new world of possibilities

- Particle sizes down to 10 µm with ± 5% deviation from the mean diameter
- Uses a water “carrier” stream
- Analogous to emulsion processes
- Requires lyophilization
- Compatible with PLGAs, PLAs, PCLs, PCHPs, alginites, gelatins, and other biopolymers
- Good for injectable small molecules, proteins, peptides, vaccines, and heat-labile molecules

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The Unisun® platform can be used with many drugs used to treat a variety of otic disorders, including Meniere's disease, sudden sensorineural hearing loss, tinnitus, and autoimmune inner ear disease. Drugs include small molecules, peptides, monoclonal antibodies, proteins, and macromolecules.

Current drug delivery systems for the treatment of inner ear diseases offer either tight control of pharmacokinetic drug levels in the inner ear or a low cost of treatment, but not both. Because the Unisun® platform combines the use of uniform drug-loaded microspheres (for precise control of drug release) along with a fast-film forming agent (allowing for low cost, intratympanic delivery of the drug) it is well positioned for widespread clinical adoption.

Unisun® leverages enhanced Stratµm® microparticles for treating the inner ear:
- Combines Stratµm® microspheres with a film forming agent, or a film-forming agent on its own
- Film-forming agent uses a non-irritating aqueous base
- Film-forming agent dries quickly on warm biological surfaces
- Can be used to inject and set up highly concentrated depots of a drug
- Good for small molecules, proteins, peptides, and vaccines

Top: Unisun® loaded into a syringe with a 27 GA needle.
Bottom: The Unisun® dose in a mouse with IR dye-loaded microspheres shows signal after administration (left), and not in ears lacking the dosage form (right).