

AHARAV CONSULTANTS



*Available with
New features -2023*

Providing services that save 60-70% time and 50-60% on costs on analysis, and data analytics



BACKGROUND

- Portfolio and product selection in SECONDS!!
- Product selection for development using the “classic” databases requires further analysis of the raw data provided. This takes a lot of time for the team to select products and can be less efficient and time consuming
- HORIZONS® tool is a interface which provides the key parameters (that can be tailored to each company) and obtain the potential candidates along with a possible road map to help taking decisions for Portfolio and Product selection activities
- The analysis and results are generated in seconds saving valuable time and cost for the end user
- The tool has been active since 2021 and now available on various flexible subscription mode





| | | | | |
|--|--|---------------------|---------------------|------------------------------|
| Customised search based on user focus areas | YES | X | X | X |
| Key strategic blue print provided? | YES | X | X | YES |
| Dynamic searches for | YES | X | X | X |
| Specific and Unique Keywords API, Formulation, Regulatory, Commercial, IP | YES | X | X | X |
| Type of products | All patented/ future generic products/ dosage forms / unique opportunities | YES | YES | YES |
| Time to design “first cut” portfolio | Seconds / Minutes | Days / Weeks | Days / Weeks | Days / Weeks |
| Subscription Models | “Drive Thru” / Monthly / Yearly Pay as you need - USER controls costs | Annual / User based | Annual / User based | Annual / User based / Module |
| Single view comparison across geographies | YES | X | X | X |
| Target launch date for Day 1 - based on all relevant patent analysis | YES – with potential strategy (analysed manually) | X | X | X |
| Geographical scope - Global Customised to user? | US EU TR SA RU AU CA JP UK MX BR - Mapped for any country on request | Global | Global | US JP BR CN EU |
| Earliest launch provided? | YES – with potential strategy | X | X | X |
| Sales data / Consumption data | “Adjusted” | YES | YES | Partly |
| Potential API and Generic competitors (Est.) | YES | X | X | X |
| Specific product search | YES | YES | YES | YES |



- Tool that Understands and delivers to your needs
- Saves 60-70% costs on databases and manhours

Proposed scope

- HORIZONS[®] and PHARMA-PET[®] that has helped many of our other clients designing a successful generic and API based product portfolio
- HORIZONS[®] is created to take quick decisions at the top level by saving 80-90% of man hours, and at 30-40% of the cost.
- HORIZONS[®] gives flexibility of choosing data based on needs, and controlling costs
- HORIZONS[®] features unique parameters for selection e.g.
 - Unmet medical needs
 - Potential blockbusters
 - Low competition selection for API and FD
 - Dosage switch strategies
 - HPAPIs
 - Dosage forms related keywords (Soft gel, unmet medical needs)
 - Exclusion criteria to focus on the end users competiancies
- The scope is to identify products for development commercial or manufacturing in **seconds**
- A separate focus on Products in clinical trials
- 5 Main parameters in portfolio selection incorporated
 - Potential Revenue
 - Developmental / Commercial timeline
 - Expected Competition post launch
 - Sources available
 - IP / Regulatory time frame
 - Approval / launch timeframe

Interactive platform – discussing and advising on portfolio selection, IP strategy, “hand holding” during development based on the end users priorities and expertise – at no further cost



Product Hits: 216 Cost for download: \$ 86,580.00 / £ 66,600.00

Dynamic Search

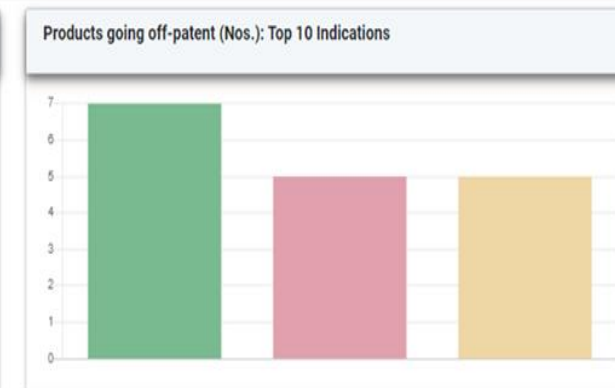
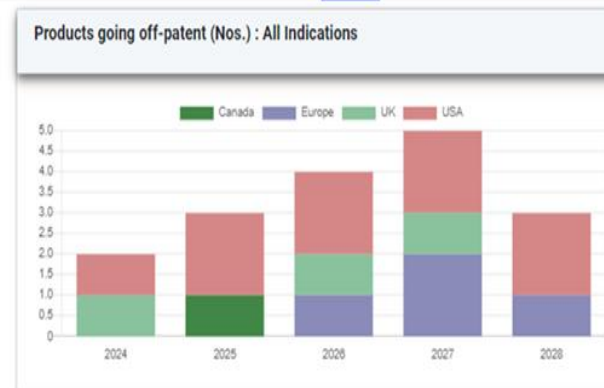
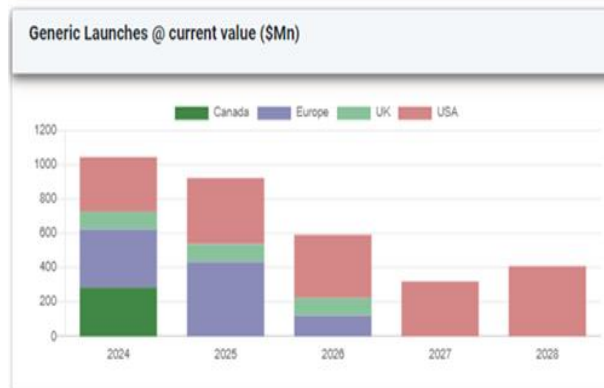
Active Filters - 8 Clear All

| Country | Earliest Gener... | Revenue (\$ Mn) | Dosage Type | Therapeutic Ca... | API Manufactur... | API Consumpti... | ANDA filers |
|----------------|-------------------|------------------|---|--|-------------------|----------------------|-------------|
| Europe 1 / 100 | 2024 1 / 110 | 0-50 69 / 201 | Drops / Solution / Liquid / Sus... 0 / 32 | Anti-diabetic / Hypoglycemia/... 1 / 79 | > 10 7 / 384 | 0-50 Kg 2 / 68 | 1-2 5 / 241 |
| USA 7 / 165 | 2025 3 / 100 | 101-500 28 / 86 | Oral Solids 8 / 413 | Blood levels / Cholesterol blood... 3 / 30 | 6-10 1 / 115 | 1-5 MT 2 / 93 | 3-5 3 / 137 |
| | 2026 4 / 136 | 501-1000 8 / 35 | | CNS / Neurological 1 / 85 | | 100 Kg - 1 MT 1 / 90 | |
| | | 51-100 6 / 34 | | Oncology / Chemotherapy 2 / 85 | | 51-100 Kg 1 / 26 | |
| | | NA 52 / 158 | | Osteoporosis / Arthritis / Bon... 1 / 14 | | NA 2 / 92 | |
| | | Over 1000 7 / 41 | | | | | |

Analysis – new features

- **Dynamic analysis** for further “deep dive” identification
- **Interactive graphical interface** for customised flowcharts and graphs within your selection

| Add | Country | Active Substance | Therapeutic Category | Indication/Innovator/Brand | Dosage Type | Strength | Revenue (\$ Mn) | Suggested Strategy/Comments | Earliest Generic Launch | Marketing Exclusivity ME/NCE/NDA | Filing Exclusivity DE/NCE-1 | Key Patents | Keywords | ANDA filers | API Manufacturers | API Consumption (Kgs) | Generics expected | Main Patent Expir |
|--------------------------|---------|---------------------|-------------------------|---|-------------|--------------------|-----------------|---|-------------------------|----------------------------------|-----------------------------|--|--|-------------|-------------------|-----------------------|-------------------|-------------------|
| <input type="checkbox"/> | USA | Lenvatinib Mesylate | Oncology / Chemotherapy | Kidney Cancer, Thyroid Cancer, Eisai, Lenvima | Oral Solids | Capsule: 4mg, 10mg | 803.12 | <p>ANDA filers: Shipla, Sun Cases consolidated</p> <p>Target generic entry in Oct 2025 with NI polymorph - <i>less likely</i></p> <p>Target launch in Sep 2026 with innovator polymorph with a skinny label and after ANDA filer triggers exclusivity - <i>more likely</i></p> <p>Potential strategy for new ANDA filer:</p> <ol style="list-style-type: none"> 1. No novel polymorph is required. 2. Launch after Sep 2026 if exclusivity is triggered by ANDA filer 3. Launch in Jul 2027 with PIV strategy <p>Comments:</p> <p>We believe that the 791 patents can be invalidated on the basis of obviousness</p> | 19/09/2026 | 13/02/2020 | 13/02/2019 | <p>US 7612208 - crystalline forms of lenvatinib mesylate - Forms A, B, C, F and I, alpha, beta - Exp 19 Sep 2026 - PIV - blocking patent</p> <p>US 9006256 - methods of using lenvatinib for the treatment of thyroid carcinoma - Exp 27 Jul 2027 - PIV NI or Section VIII</p> <p>US 10259791 / US 10407393 / US 11186547 - high purity lenvatinib with certain impurities less than 60ppm or 183ppm - Exp 26 Aug 2035 PIV NI or PIV invalidation</p> <p>US 11090386 administering a suspension wherein the basic substance is present in an amount effective for suppressing bitterness of the compound PIV VI Exp 23 Feb 2036 - PIV NI not related to capsule</p> | API Class - HPAPI, API type - Cytotoxic drug, Competition - 5 DMFS / EDMFs | 1-2 | 6-10 | 78 | 3-5 | 23/10 |



Super-Keywords

Advanced Search - Keywords

API

- API Class - HPAPI
- API Class - Low solubility (BCS 2/ BCS 4)
- API type - Animal source
- API type - Cephalosporin
- API type - Control substance
- API type - Cytotoxic drug
- API type - Hormone
- API type - Oligonucleotide
- API type - Penems
- API type - Peptide
- API type - Radiopharmaceutical
- API type - Sterile
- API type - Steroid
- API type - Veterinary
- BLA component
- Chemistry - Chiral
- Chemistry - Complex
- Chemistry - Fermentation
- Chemistry - Fluorine based
- Competition < 5 DMFS / EDMFs
- Competition - No API sources
- Competition <5 JPDMFs

Technology

- DF - Film
- DF - Inj - Lyophilised
- DF - Inj - PFS / Pen
- DF - Inj - RTU
- DF - Ophthalmic- Drops / Liquid
- DF - Oral Capsule - Soft Gel
- DF - Oral Solution / Suspension
- DF - Oral Tablet - Sublingual / Buccal
- DF - Powder - Inhalation
- DF - Powder / Granules - oral
- DF - Tablet - Chewable / gum
- DF - Tablet - Effervescent
- DF - Tablet - ODT
- Drug Product - Combination (FDC / Adjuvant / Co-packaged)
- Drug Product - Difficult to formulate
- Manufacturing - Special facility
- Route - Administered Using Device
- Route - Device - Inhaler / MDI / DPI / Nebuliser
- Route - Modified Release (XR / DR / SR)
- Route - Reconstitution required
- Technology (Inj / Ophthalmic / Spray) - Emulsion
- Technology (Inj) - Liposomal
- Technology (Inj) - Microsphere
- Technology (Inj) - Nanoparticulate

Regulatory

- Approved in 2021 (EU)
- Approved in 2021 (US)
- Approved in 2022 (EU)
- Approved in 2022 (US)
- Approved in 2023 (EU)
- Approved in 2023 (US)
- Orphan / Rare disease (US)
- Orphan / Rare disease - (EU)
- Orphan / Rare disease - (JP)
- OTC
- PDUFA / CGMP / Approval watch (US/EU)
- Phase 1
- Phase 2 (US)
- Phase 3-4 / (US)
- Recent approvals - 21/22 (JP)
- REMS
- Repurposing / secondary indication
- Specific bio guidance
- Strategy - Dosage switch opportunity
- Strategy - New dosage / strength opportunity

IP

- 180 - Day Launch Strategy (US)
- AAA* rated
- FTF opportunity - GAIN (US)
- FTF opportunity - NCE (US)
- FTF opportunity - NDA / Open FTFs / No ANDA filers -(US)
- IP - Alt salt / solvate / hydrate advantage
- IP - Polymorph adv (EU)
- IP - Polymorph adv (JP)
- IP - Polymorph adv (US)
- IP - Process adv (EU)
- IP - Process adv (US)
- IP- Particle size constraint
- Monitor litigation (US)
- Monitor NCE date
- Monitor OB listing
- Monitor opposition (EPO)
- Monitor Paediatric Extn (EU)
- Monitor PTE (US)
- Monitor SPC (EU)
- Monitor SPC (UK)
- No OB patents
- Recent OB Patent listing
- Unknown ANDA filers present

Commercial

- Blockbuster watchlist
- First in class
- Generic available (EU)
- Generic available (US)
- Generic launch on approval (UK / EU)*
- Launch on approval - no blocking patents (US) *
- Limited Launch (EU)
- Not Approved (EU)
- Not Approved (UK)
- Not Approved (US)
- Other dosage forms available
- Refused / Withdrawn (EU)
- Refused / Withdrawn (US)
- Small market (EU)
- Small market (JP)
- Small market (WW)
- Strategy - Early FD development
- Strategy : 505b(2)(US only)
- Strategy- API opportunity
- Unmet need (India)

- SUPER KEYWORDS with Inclusion Or Exclusion criteria

Competitive Intelligence (Available for US, Europe & UK)

Number of API Manufacturers (Global)

- All 0 1-2 3-5 6-10 > 10

Revenue (\$Mn Regional)

- All 0-50 51-100 101-500 501-1000 > 1000

Number of ANDA filers (US)

- All 0 1-2 3-5 6-10 > 10

Number of generics expected

- All 0 1-2 3-5 6-10 > 10

API Consumption (Global)

- All 0-50 Kg 51-100 Kg 100 Kg - 1 MT 1-5 MT 5-10 MT 10-25 MT 25-50 MT > 50 MT

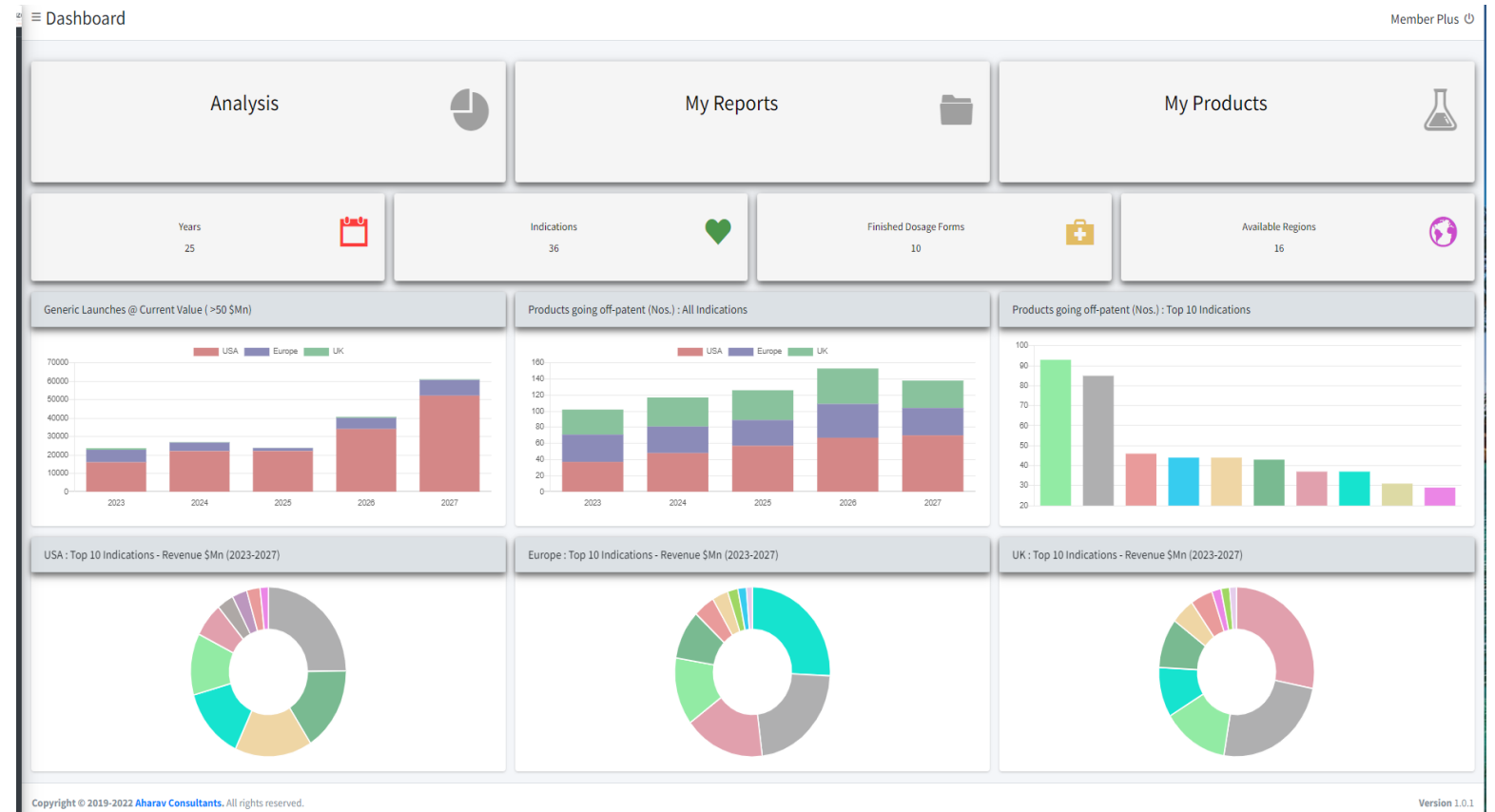
Save your search

Search



Usability – new features

- “My-Reports”- Create your own product list for downloading
- Generate customised reports
- Interactive interface for customised flowcharts and graphs within your selection





Portfolio designing

Time bound subscription

Hybrid

Free user subscription

Yearly / Monthly / Drive Thru

Onscreen Access

Customised Download

Buy what you need

Excel download

Download ("add on feature")

Onscreen access

Cost controlled by user



Extended services in partnership



Core Services

Business Development / Commercials

Licensing (in & out)

- Complex generics
- Biosimilars
- 505(b)(2)
- OTC
- Devices
- Nutraceuticals

M&A

- Corporate development/Divestiture strategy
- Specific acquisition criteria & strategic fit
- Potential targets/acquisition candidates
- Manage NBOs, Due diligence & valuation
- Negotiations & Conclusion of agreements

Asset Sales & Purchases

ANDAs / Marketing authorisations

Non-Technical Services

- Intellectual property management
- Legal support
- Human resource
- Financial advisory
- Strategic sourcing



Customer base - wall



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