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| D | Project Name | VACAVILLE GRASSROOT FILL/FINISH PROTEIN-BASED ANTI CANCER | PEC Activity Diagram | | | |
| | Industry Code | 13 Pharmaceutical & Biotech | Project Type Grassroot | | | |
| | TIV (USD) | 80,000,000 | | | | |
| | SIC Code | 2836 Biological Products, Except Diagnostic Substances | Sector Final Formulation (Oral, Solid, Parenteral, Topical, etc.) | | | |
| | SIC Product | 2836*0036 Aseptic Fill and Finish - Ampoules, Cartridges, Syringes, Vials | | | | |
| | Status | Active | Last Update | 31-Jan-2022 | Initial Release | 27-Jan-2022 |
| | Environmental | Air (A) Land (L) Water (W) | Construction Labor Preference Union, Non-Union | | Operations Labor Preference Non-Union | |
| | Plant Owner | Polaris Pharmaceuticals Incorporated | Plant Parent Polaris Group Limited | | | |
| | Plant Name | Vacaville Fill/Finish/Protein-Based Anti Cancer CDMO | Unit Name | | | |
| | Plant ID | 3493136 | Phone | | +1 707 451 0441 | |
| Location | Intersection of Interstates 80 and 505, Vaca Valley Business Park | Zone/County | | CA*03, Solano | | |
| City/State | Vacaville, California 95688 U.S.A. | | | | | |
| Project Responsibility | Project Company | Project Contact | | | | |
| Project Director | Polaris Pharmaceuticals Incorporated 4941 Allison Parkway Vacaville, California 95688 U.S.A. | Chris Huxsoll VP Operations [Tel.] +1 707 451 0441 x112 / [Alt.] +1 530 902 4848 (Mobile) [E-Mail] chuxsoll@polarispharma.com ; [LinkedIn] chris-huxsoll-555a631 | | | | |
| Project Manager | Polaris Pharmaceuticals Incorporated 4941 Allison Parkway Vacaville, California 95688 U.S.A. | Matt Mitchell Director of Facilities [Tel.] +1 707 451 0441 x103 / [Alt.] +1 707 724 2760 (Mobile) [E-Mail] mmitchell@polarispharma.com ; [LinkedIn] mitchellcon | | | | |
| Specification and Reliability | Polaris Pharmaceuticals Incorporated 4941 Allison Parkway Vacaville, California 95688 U.S.A. | Daniel Wood Senior Production Manager [Tel.] +1 707 451 0441 [E-Mail] dwood@polarispharma.com ; [LinkedIn] daniel-wood-861229209 | | | | |
| A&E | CRB Engineering Incorporated 6001 Shellmound Street Suite 550 Emeryville, California 94608 U.S.A. | Trevor Auer Project Manager [Tel.] +1 510 907 2701 [E-Mail] trevor.auer@crbgroup.com ; [LinkedIn] trevor-auer-3b24376 | | | | |
| PEC® Timing | P1 | PEC® Activity Preliminary Design | | | | |
| Project Probability | Medium (70-80%) | | | | | |
| Scope | Polaris Pharmaceuticals Incorporated with CRB Engineering Incorporated (Conceptual Architect) performs Preliminary Design for Grassroot Fill/Finish & Protein Based Anti-Cancer Therapeutics CDMO Plant. DETAILS: Within Vaca Valley Business Park, near the intersection of Interstates 80 and 505, on recently purchased (from Agenus) 15-acre site, construct building(s) (size to be-determined) and equip for the proprietary and contract R&D, QC and production of protein-based novel anti-cancer therapies (including the proprietary Pegargininase ADI-PEG 20, which is in late-stage clinical development) plus temperature controlled warehouse. REQUIRES: Building(s), Building Management Systems (BMS), Building Automation Systems (BAS), Temperature and Humidity Controls, Fire and Security System, Air/Gas Vacuum System, Refrigeration, Freezers, Conveyors (Belt/Roller), Industrial Gas Supply and Storage, Voice/Data/Wireless System, Fermentation Equipment, Centrifuges, Microfluidizers, Harvest & Holding Vessels, Buffer Preparation Tanks, Chromatography Skids, Tangential Flow Filtration (TFF) Systems, Aseptic Fill/Finish Equipment (Vials), Visual Inspection Equipment, Cleanrooms (ISO 5-7/Class 100-10,000), Cell Lysis Equipment, Water-For-Injection System, Laboratory Stations, Analytical Equipment, Data Recorders, Checkweighers, Automated Clean-In-Place Skids, High Purity Piping, Clean Steam Generators, Compressors (Air), Material Handling Equipment, Automated Retrieval Systems, Controls (PLC, DCS), NGF Boiler, Chiller, Cooling Tower, Heat Exchangers, Electrical Distribution, Water Purification System, Emergency Generators, Uninterrupted Power Supply, Pumps, Motors, Valves. ENVIRONMENTAL: (A) HEPA Filtration System, Fume Hoods, Dust Collectors; (L) Containment; (W) Pre-Wastewater Treatment System, Stormwater Drainage System. | | | | | |
| Schedule | Polaris Pharmaceuticals Incorporated with CRB Engineering Incorporated (Conceptual Architect) continues with Preliminary Design through 3Q22 (Aug). Upon FDA approval of Pegargininase ADI-PEG 20 (In Phase III clinical-trials), Polaris awards principal A/E 3Q22 (Aug-Sep). Upon substantial completion of Design, Polaris with A/E selects G/C 1Q23 (Jan-Mar). Upon selection Polaris with G/C releases any remaining Equipment RFQs plus Subcontractor Bid Documents 1Q23 (Mar)-2Q24 (Jun). Tentative Construction Kick-Off 2Q23 (Apr), Project Completion 4Q24 (Dec). **NOTE: THERE IS A PAUSE IN THIS PROJECT. POLARIS IS AWAITING FDA APPROVAL FOR PEGARGININASE ADI-PEG 20 THAT IS IN PHASE III CLINICAL TRIALS; SHOULD HAVE RESULTS BY LATE SUMMER EARLY FALL 2022. TIV AND PROJECT CONSTRUCTION/BID AND VENDOR SELECTION TIMELINES ARE ESTIMATED.** | | | | | |
| Project Milestones | AFE 202208 | Sub Bid Doc 202303 | Completion 31-Dec-2024 | Precision YEAR | | |
| | Equip RFQ 202303 | Kick-Off 202304 | Kickoff Slippage 4 Months | Duration 21 Months | | |
| Engineering | Civil | Electrical | Environmental HVAC | Instrumentation | Mechanical Structural Process | |



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|--------------------------|-----------------|--------------------------|---------------|--------------|-----------------|---------------|------------|---------------|
| Contracting | Civil | Electrical | Environmental | HVAC | Instrumentation | Mechanical | Structural | General [G/C] |
| Project Key Needs | Civil/Site | Structural | Architectural | Control Room | Process Equip | Heat Transfer | | |
| | Instrumentation | Electrical | Mechanical | HVAC | Storage | | | |
| | Piping/Fittings | Insulation/Coatings | Environmental | Utilities | Valves | | | |
| | Communications | | Batch Process | | Packaging | | | |
| Matter Phase | | Material Handling | | | | | | |
| Energy | | Liquid | | | Solid | | | |
| Buy | | Boiler | | | Generator | | | |
| Sell | | | | | | | | |

| Plant Standard Contacts | | | |
|-------------------------|----------------------------|---------------------------------------------------------------|-----------------------|
| Functional/Actual Title | Contact Name/E-mail | Telephone/On-site | QC Date/LinkedIn ID |
| Plant Manager | Chris Huxsoll | [Phn.] +1 707 451 0441 x112 / [Alt.] +1 530 902 4848 (Mobile) | Jan-2022 |
| VP Operations | chuxsoll@polarispharma.com | No | chris-huxsoll-555a631 |

| Historical Reports | | | | |
|----------------------------------------------------------------------------------|-------------|----------------|--------------------------|--|
| Project Name | Report Date | TIV | Phase | |
| VACAVILLE GRASSROOT FILL/FINISH PROTEIN-BASED ANTI CANCER THERAPEUTIC CDMO PLANT | 27-Jan-2022 | 80,000,000 USD | Preliminary Design (P1 - | |
| VACAVILLE GRASSROOT FILL/FINISH PROTEIN-BASED ANTI CANCER THERAPEUTIC CDMO PLANT | 28-Jan-2022 | 80,000,000 USD | Preliminary Design (P1 - | |
| VACAVILLE GRASSROOT FILL/FINISH PROTEIN-BASED ANTI CANCER THERAPEUTIC CDMO PLANT | 28-Jan-2022 | 80,000,000 USD | Preliminary Design (P1 - | |
| VACAVILLE GRASSROOT FILL/FINISH PROTEIN-BASED ANTI CANCER THERAPEUTIC CDMO PLANT | 31-Jan-2022 | 80,000,000 USD | Preliminary Design (P1 - | |

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