PHARMACEUTICAL PATENT LICENSE & DRUG ROYALTY AGREEMENT

Exclusive Drug Compound and Manufacturing Process License

License Agreement No: PHARM-2024-DRG-7394
Effective Date: April 15, 2024
License Classification: Exclusive Manufacturing and Distribution Rights
FDA Drug Master File: DMF-047382 | **EU EMA Reference:** EU-CTA-392847

CONTRACTING PARTIES

LICENSOR (Drug Patent Owner/Research Company)

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Corporate Information:
Federal EIN: 56-7394820
Delaware LLC Registration: 7394820
FDA Establishment ID: 10847382
DEA Registration: RB7394820

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LICENSEE (Pharmaceutical Manufacturer)

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Indiana Corporation ID: 8472936
FDA Establishment ID: 19472836
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ISO 13485:2016 Certified

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⚠ **FDA REGULATORY NOTICE: This agreement covers prescription pharmaceutical products subject to FDA oversight. All manufacturing, testing, and distribution activities must comply with current Good Manufacturing Practices (cGMP), FDA regulations, and applicable international pharmaceutical standards.**

1. LICENSED DRUG COMPOUNDS AND INTELLECTUAL PROPERTY

1.1 Licensed Drug Portfolio: Licensor hereby grants Licensee exclusive manufacturing and distribution rights for the following patented pharmaceutical compounds and formulations:

Primary Drug Compound Patents:

Drug Name/Code	Therapeutic Class	Patent Numbers	Patent Expiration	Regulatory Status
CardioCure-XR™ (BRI-CC-2019)	ACE Inhibitor Hypertension	US 11,847,293 EP 3,947,582	August 12, 2039 March 15, 2040	FDA Approved NDA 218473
DiabetesShield-24™ (BRI-DS-2020)	SGLT2 Inhibitor Type 2 Diabetes	US 11,925,847 JP 7,294,583	January 28, 2040 June 4, 2040	FDA Approved NDA 219847
NeuroRestore-Plus™ (BRI-NR-2021)	NMDA Antagonist Alzheimer's Disease	US 12,074,391 CN 116,847,392	September 16, 2041 November 22, 2041	FDA Phase III IND 147382
ImmunoGuard-Pro™ (BRI-IG-2022)	Monoclonal Antibody Autoimmune Disorders	US 12,156,749 WO 2023/047382	December 7, 2042 Pending	FDA Phase II IND 152847

PainRelief-ER™ (BRI-PR-2023)	Non-Opioid Analgesic Chronic Pain	US 12,294,857 EU Pending	March 30, 2043 TBD	FDA Phase I IND 158392

Manufacturing Process Patents:

- **US Patent 11,738,294:** "Continuous Flow Synthesis Method for Small Molecule APIs" (Expires: May 15, 2039)
- **US Patent 11,625,847:** "Advanced Crystallization Process for Enhanced Bioavailability" (Expires: September 22, 2039)
- **US Patent 11,483,729:** "Sterile Fill-Finish Process for Injectable Biologics" (Expires: February 8, 2040)
- **US Patent 11,356,482:** "Extended Release Coating Technology for Oral Dosage Forms" (Expires: July 11, 2040)

1.2 **Proprietary Formulations and Trade Secrets:** License includes access to:

- **BioEnhance™ Delivery System:** Proprietary drug delivery technology for improved bioavailability
- **StabilityMax™ Formulation:** Extended shelf-life formulation methods and stabilizing agents
- **QualityPro™ Testing Protocols:** Analytical methods and quality control procedures
- **ScaleUp-Optimized™ Process:** Commercial-scale manufacturing optimization parameters

1.3 **Regulatory Data and Documentation:** Licensor grants access to regulatory submissions, clinical trial data, and manufacturing documentation for approved products, subject to confidentiality and regulatory requirements.

2. TERRITORIAL RIGHTS AND MARKET EXCLUSIVITY

2.1 **Licensed Territory:** Licensee receives **exclusive manufacturing and distribution rights** within the following geographic markets:

- **Primary Territory:** **United States and Canada** (full exclusivity for all licensed products)

- **Secondary Territory:** **European Union and United Kingdom** (exclusive for CardioCure-XR and DiabetesShield-24)
- **Expansion Territory:** **Australia, New Zealand, and Japan** (non-exclusive, premium royalty rates)
- **Restricted Territory:** China, India, Brazil, and Russia (separate licensing agreements required)

2.2 Market Segment Rights:

- **Prescription Market:** Full rights for physician-prescribed medications
- **Hospital/Institutional:** Exclusive rights for hospital formulary and institutional sales
- **Specialty Pharmacy:** Exclusive distribution through specialty pharmacy networks
- **OTC Conversion:** Right of first refusal for over-the-counter formulation development

2.3 License Term and Renewal:

- **Initial Term:** **Fifteen (15) years** from April 15, 2024
- **Extension Options:** Two successive five (5) year renewal periods at Licensee's option
- **Patent Life Extension:** Automatic extension to match longest patent expiration date plus regulatory exclusivity periods
- **Data Exclusivity:** Rights continue through FDA data exclusivity periods (5-12 years post-approval)

3. ROYALTY STRUCTURE AND PRICING TERMS

3.1 Net Sales-Based Royalty Structure: Licensee shall pay royalties based on Net Sales of Licensed Products according to the following tiered structure:

Tier 1 - Approved Prescription Drugs (CardioCure-XR, DiabetesShield-24):

Annual Net Sales Range	Royalty Rate	Minimum Annual Payment	Launch Year Adjustment
$0 - $50 million	**8.5%**	$2,500,000	-2% first 18 months
$50M - $200 million	**12.5%**	$5,000,000	Standard rate
$200M - $500 million	**15.0%**	$12,500,000	Standard rate

Above $500 million	**18.5%**	$25,000,000	+1% blockbuster bonus

Tier 2 - Phase III and Late-Stage Pipeline (NeuroRestore-Plus):

Development Stage	Base Royalty Rate	Risk Adjustment	Effective Rate
Phase III Clinical Trials	15.0%	-5% risk discount	**10.0%**
FDA Review (Post-NDA)	15.0%	-2.5% risk discount	**12.5%**
FDA Approval + Launch	15.0%	Standard rate	**15.0%**
Post-Marketing Surveillance	15.0%	+2% success bonus	**17.0%**

Tier 3 - Early Stage and Specialty Products (ImmunoGuard-Pro, PainRelief-ER):

Product Category	Development Royalty	Commercial Royalty	Orphan Drug Bonus
Monoclonal Antibodies	5.0% (during development)	**20.0%**	+5% if orphan designation
Novel Analgesics	6.0% (during development)	**18.0%**	+3% breakthrough therapy
Personalized Medicine	7.5% (during development)	**22.5%**	+7% companion diagnostic

3.2 Geographic Market Adjustments:

- **Primary Territory (US/Canada):** Standard rates as specified above
- **European Markets:** **+15% premium** due to regulatory complexity and market access challenges
- **Asia-Pacific Markets:** **+25% premium** for non-exclusive territories
- **Generic Competition Adjustment:** **-50% royalty reduction** upon first generic market entry

3.3 **Net Sales Definition:** "Net Sales" means gross invoice price less: (a) trade discounts not exceeding **15%**, (b) returns and allowances, (c) rebates to government and insurance payers, (d) chargebacks and prompt payment discounts, (e) taxes and duties, and (f) freight and shipping costs.

4. UPFRONT PAYMENTS AND DEVELOPMENT MILESTONES

4.1 **Initial License Fee:** Licensee shall pay a non-refundable license fee of **$15,000,000** within 60 days of Agreement execution, providing access to approved drug formulations and regulatory documentation.

4.2 **Technology Transfer and Manufacturing Setup:**

Technology Component	Fee Amount	Deliverables	Timeline
Manufacturing Process Transfer	$3,500,000	Process parameters, equipment specifications, SOPs	6 months
Analytical Method Transfer	$1,250,000	Testing protocols, validation data, reference standards	4 months
Regulatory Documentation	$2,750,000	DMF transfer, manufacturing supplements, CMC data	3 months
Training and Technical Support	$1,500,000	On-site training, process optimization, troubleshooting	12 months

Total Technology Transfer Investment: $9,000,000

4.3 **Development and Regulatory Milestones:**

Milestone Event	Payment Amount	Applicable Products	Payment Due
Phase III Trial Initiation	$2,500,000	NeuroRestore-Plus	30 days post-initiation
FDA NDA Submission	$5,000,000	All pipeline products	45 days post-submission
FDA Approval	$10,000,000	Each approved product	60 days post-approval
First Commercial Sale	$7,500,000	Each launched product	90 days post-launch

$100M Annual Sales Achievement	$15,000,000	Per product reaching milestone	120 days post-achievement
Orphan Drug Designation	$3,000,000	Applicable specialty products	60 days post-designation

4.4 Annual Maintenance and Support: Ongoing regulatory support, pharmacovigilance, and technical assistance for **$750,000 annually** per approved product, covering:

- Regulatory correspondence and FDA communication support
- Pharmacovigilance and adverse event reporting assistance
- Manufacturing troubleshooting and process optimization
- Regulatory intelligence and competitive landscape monitoring

5. MANUFACTURING AND QUALITY REQUIREMENTS

5.1 Good Manufacturing Practice (GMP) Compliance:

- **FDA cGMP:** All manufacturing must comply with 21 CFR Parts 210 and 211
- **ICH Guidelines:** Adherence to ICH Q7 (API manufacturing) and Q10 (quality systems)
- **ISO 13485:2016:** Medical device quality management systems for combination products
- **Facility Inspections:** FDA, EMA, and other regulatory authority inspection readiness

5.2 Production Volume and Supply Commitments:

- **Year 1-2:** Minimum production capacity of 50 million units annually across all products
- **Year 3-5:** Scale to 150 million units annually with market demand responsiveness
- **Year 6+:** Maintain sufficient capacity to meet 95% of forecast demand within 90 days
- **Emergency Supply:** Maintain 6-month strategic inventory for critical medications

5.3 Quality Standards and Specifications:

- **Product Quality:** All products must meet or exceed specifications in approved NDAs
- **Impurity Limits:** Maintain impurity levels below **0.05%** for known impurities, **0.03%** for unknown
- **Potency Requirements:** API potency between **95-105%** of labeled claim
- **Shelf Life:** Minimum **24-month shelf life** for all commercial products

- **Batch Release:** 100% batch testing and quality person release prior to distribution

5.4 Supply Chain and Raw Material Requirements: