



# Developing Biologic Therapy for Solid Tumors & CIPN

Non-Confidential Deck

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Experienced Drug Development Leadership:  
Leveraging domain expertise to progress an innovative modality for an emerging target



**Scott Shively**  
President & CEO



**Ray Takigiku, Ph.D.**  
Founder and Chief Scientific Officer



**Joyce LaViscount**  
Chief Financial Officer



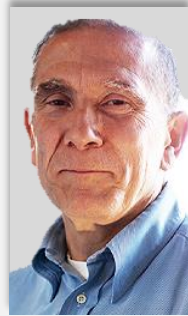
**Jim Beach**  
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**Christy Rothwell, J.D., Ph.D.**  
IP, Legal Advisor



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VP, Chemistry, Manufacturing & Controls



**Gilles Tapolsky, Ph.D. M.B.A.**  
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**Richard C. Curry III, MD**  
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Commercialization Advisor





Bexion is a clinical-stage  
biopharmaceutical company  
developing a novel biologic  
to treat mCRC and CIPN  
patients in need of effective  
treatments

## Investment Highlights

- **BXQ-350 demonstrated Early Clinical Safety & Efficacy Evidence**
  - Completed adult & pediatric Phase 1 oncology studies
  - **Excellent safety profile** allowing combination treatment
  - **Phase 1b/2 trial** of BXQ-350 + SOC for the treatment of newly diagnosed **metastatic colorectal cancer** (mCRC)
  - Preclinical & clinical evidence also suggests that **BXQ-350 could prevent/reverse chemotherapy-induced peripheral neuropathy (CIPN)**
- **Large, Unmet Need**
  - In mCRC, there has been little innovation in the past 20 years for patients who are not candidates for biomarker-driven therapy
  - POC trial in CIPN explores first potential disease-modifying effect
  - Opportunity to expand to other neuropathies
- **Unique drug product toward new but studied target**
  - Emerging understanding of **sphingolipid metabolism** in cancer & neurological disease
  - Novel formulation provides **strong IP protection through at least 2038**

**Raised over \$106M (\$100M in private funds with an additional \$6.1M in grants, including from the National Cancer Institute)**



# Metastatic Colorectal Cancer

# Opportunity for impact in Metastatic Colorectal Cancer (mCRC)



**153,000 newly-diagnosed CRC patients in the US in 2023, 23% are metastatic at diagnosis, and more will become so**

## **Large Eligible Patient Population**

**~30-35%  
of 1L mCRC patients are  
candidates for BXQ-350**


Base case adoption projections in 1L<sup>1</sup>  
Upside expansion into 2L  
combination

## **Strong Value Proposition**

**In combination with  
generic chemotherapy  
agents, BXQ-350 will  
provide meaningful clinical  
benefit with less budget  
impact than multiple  
branded drug regimens**

## **Clinical Benefit Built on SOC**

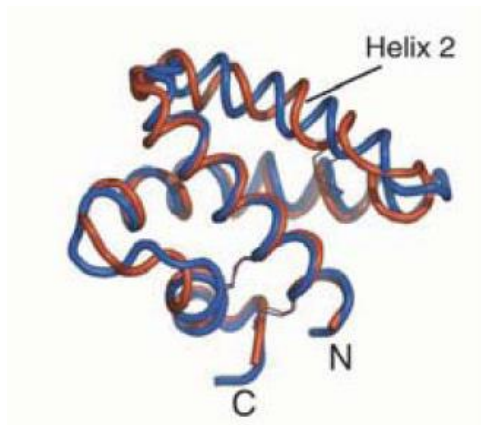
**Enabling a higher dose of  
oxaliplatin could add  
synergy in overall response  
to treatment and  
improvement in patient  
outcomes**



**BXQ-350**  
**A Novel Biologic**  
**Targeting Sphingolipid Metabolism**



## Active Ingredient

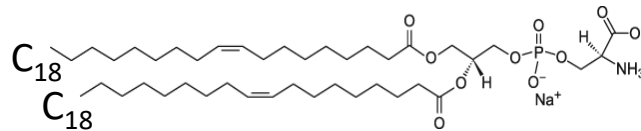


### Sphingolipid Activator Protein, **SapC**

- 80 amino acids, 9 kDa
- Analog of natural human protein

+

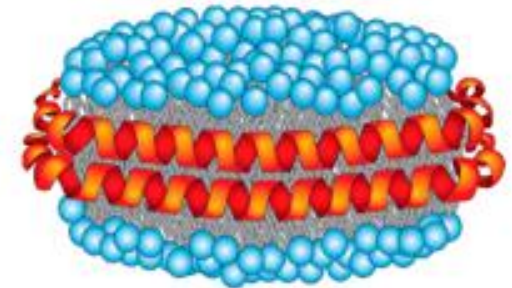
## Key Formulation Ingredient



- Form of Phosphatidylserine (**PS**)
- Mimics lipids on cell surfaces for targeting

=

## SapC-PS Nanovesicle

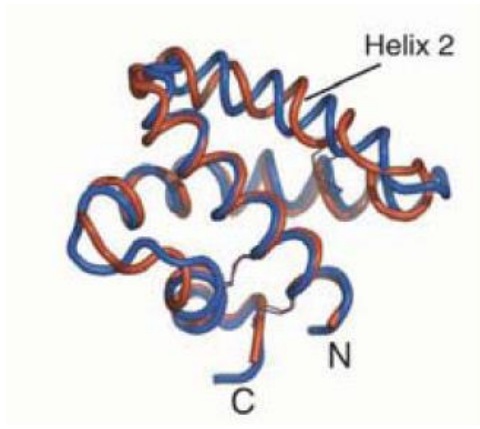


- Formulated with inert excipients to produce a new Biologic Product (BXQ-350)

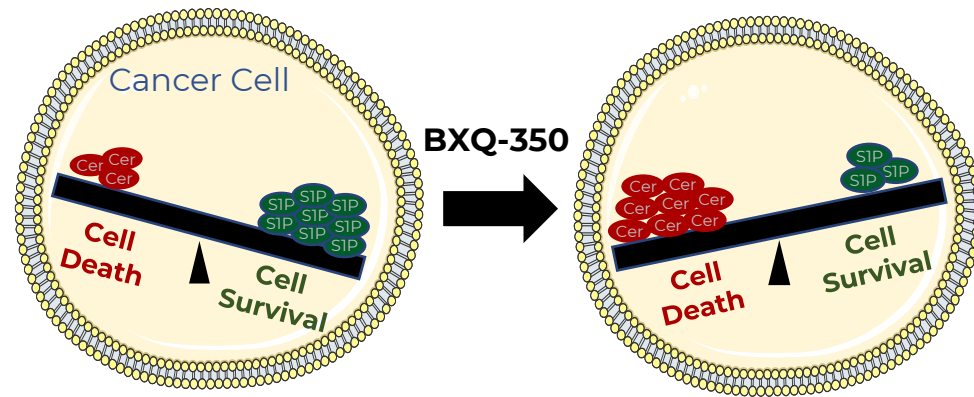


# BXQ-350 Activates Sphingolipid Metabolism:

BXQ-350 is a lipid nanovesicle of Saposin C, a protein that activates sphingolipid metabolism



**Saposin C allosterically activates several enzymes involved in sphingolipid metabolism**



**BXQ-350 Increases:**  
 Programmed Cell Death,  
 Blocks proliferation,  
 Restores Homeostasis,  
 Immune Stimulation

**BXQ-350 Reduces:**  
 SIP Receptor Signaling,  
 Inflammation, Immune  
 Suppression, CIPN

**Cer Ceramide:** pro-apoptotic, immunoeffector

**SIP SIP:** cancer proliferation, immunosuppressor

**Dysregulated SIP is**  
 associated with worse  
 outcomes in CRC and  
 oxaliplatin-induced  
 peripheral neuropathy<sup>1</sup>

# Phase 1 Monotherapy Study – Excellent Safety, Efficacy Evidence

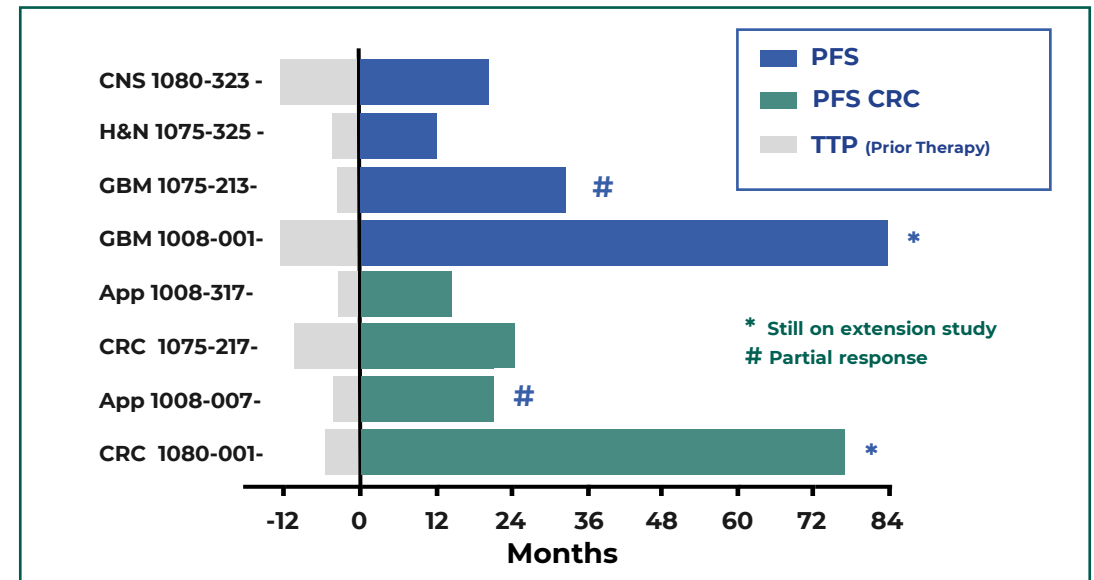


## Excellent Safety Profile

- ✓ Biologically Effective Dose identified
- ✓ **No target organ toxicity**; only 1 SAE (infusion reaction) in over 1000 doses as monotherapy
- ✓ No change in clinical chemistries, hematologic or coagulation parameters
- ✓ Safety profile suggests possibility of **combination approach**
- ✓ 73 patients received more than 1 cycle in all-comers Phase 1
- ✓ 20 different tumors represented in the study

## Initial Efficacy

- ✓ Heavily pre-treated, end stage patients, achieved stable disease or PR:
  - 13 patients at Cycle 4 (17.8% of evaluable patients)
  - 8 Patients at Cycle 8 (11.0% of evaluable patients)
- ✓ Patients with durable Stable Disease (PFS > 6, 12, 24, & 60+ months):

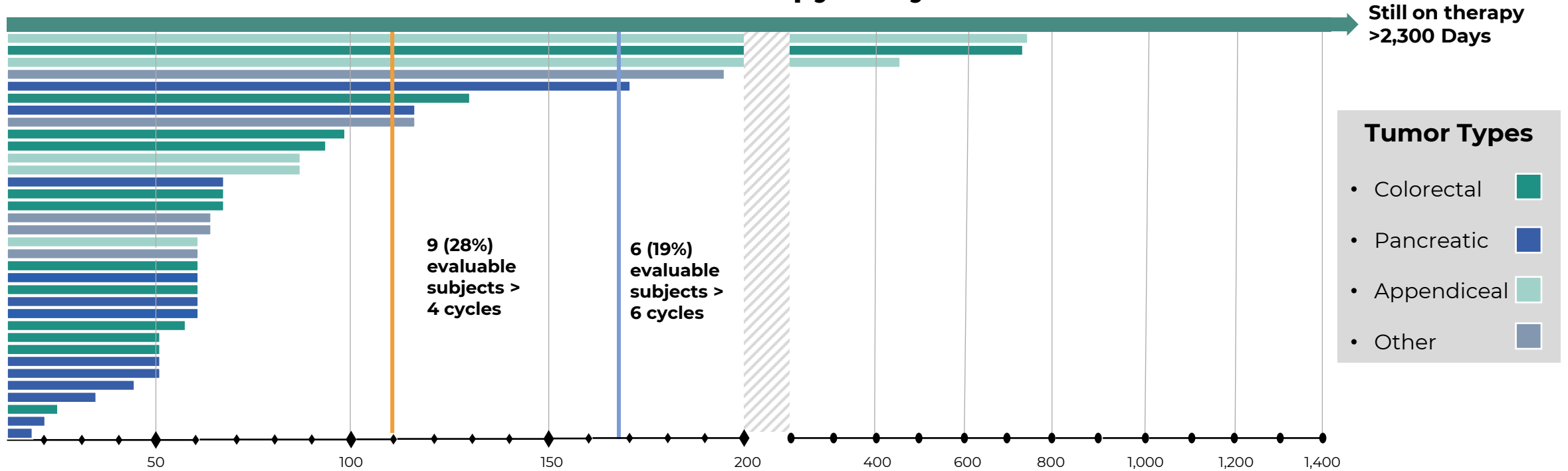


# GI Cancer Subset of Phase 1 Monotherapy Study

## Colorectal Cancer a Promising Focus



### Time on Therapy - Days



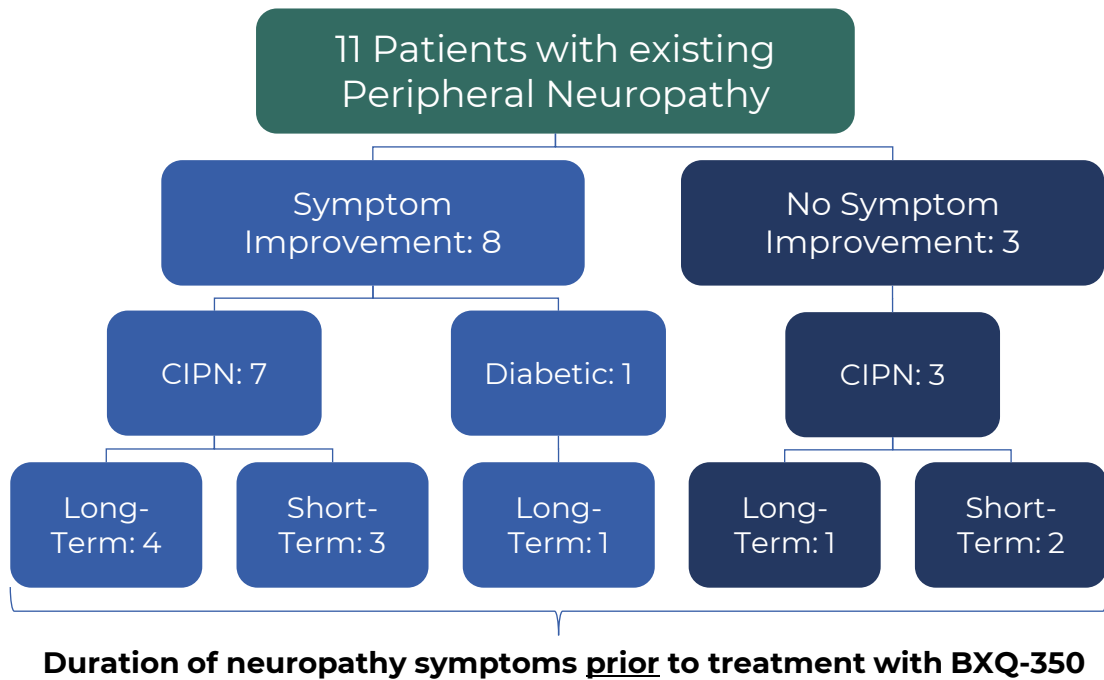
**Maximum duration of response: 318+ weeks**  
**32 GI patients in study**  
**Heavily Pretreated (end-stage) Patients**

# Chemotherapy Induced Peripheral Neuropathy Opportunity

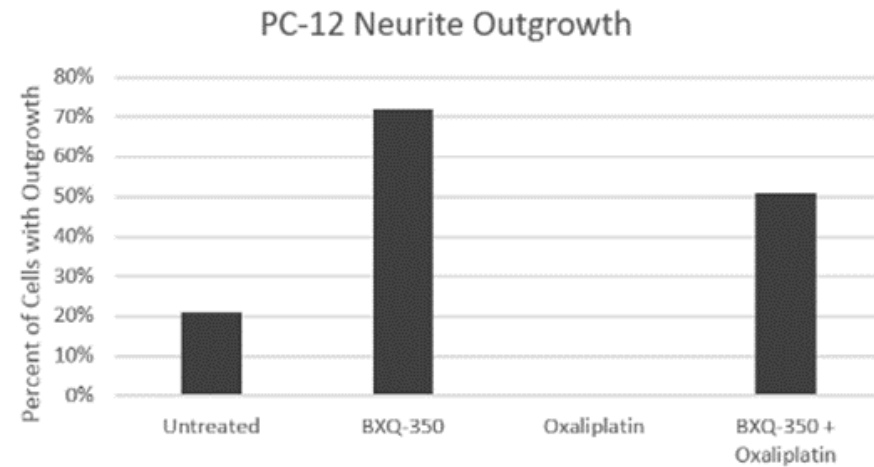
## Phase 1 Findings and Preclinical Data



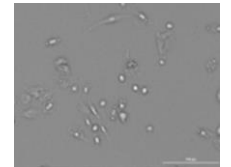
Patients in the Phase 1 study anecdotally reported resolution or improvement of long and short-term neuropathy. After retrospective investigation, the majority of afflicted patients improved:



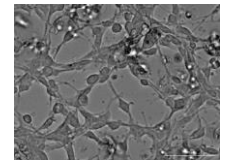
*In vitro* data suggest the potential for **disease-modifying** effect



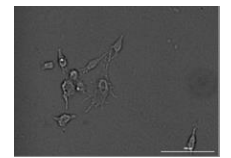
Cell Culture



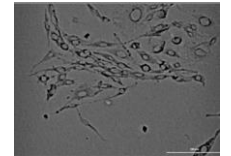
Untreated Cell Growth



Low-Dose BXQ-350 (50nM)



Oxaliplatin



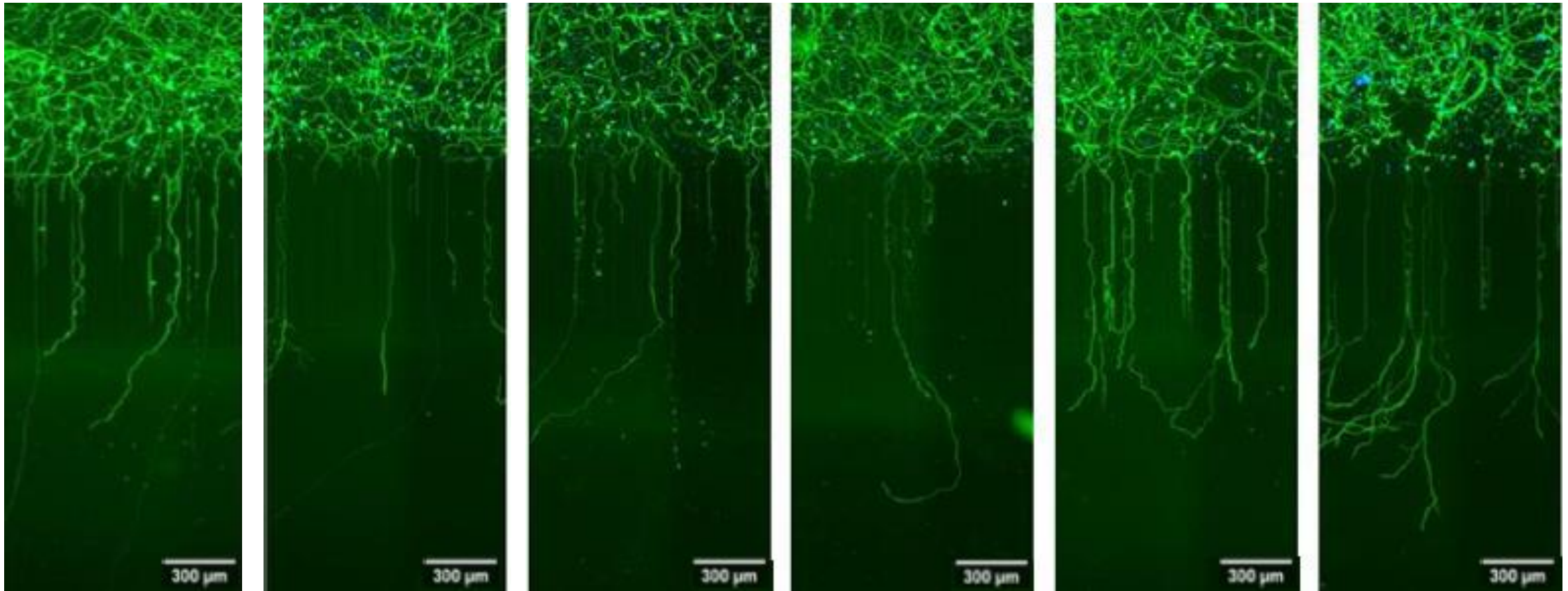
Oxaliplatin + BXQ-350

- Pre-clinical data provides potential rationale for neuropathy resolution observed during the Phase 1 clinical study of BXQ-350 (8 of 11 patients with peripheral neuropathy reported improvement)
- BXQ-350 promoted neurite outgrowth *in vitro*, even in the presence of oxaliplatin, which normally halts neurite outgrowth

# BXQ-350 promotes nerve cell health & growth and reduces damaging effects of chemotherapy



In Ananda NeuroHTS™, an imaging assay assessing numerous neuron and axon characteristics, BXQ-350 demonstrates dose-dependent neuron growth and protection against paclitaxel



Control

100 nM Ptx

Ptx + 100 nM BXQ

Ptx + 200 nM BXQ

Ptx + 500 nM BXQ

Ptx + 1000 nM BXQ

# Pipeline Currently Focused on Solid Tumors and CIPN



Clinical Trials		Preclinical	Phase 1	Phase 2	Comments
<b>Cancer Indications</b>					
Newly Diagnosed mCRC – CIPN Endpoints	FOLFOX + BXQ-350	→			FPFD-Jan 9, 2023, 21 subjects dosed
DIPG/DMG - Pediatric	BXQ-350 + Radiation	→			Dosed 8 of 10 subjects
<b>Non-Cancer Indications</b>					
PoC CIPN Study	BXQ-350	→			FPFD- Oct 17, 2022, 13 subjects dosed

**Multiple Indication Expansion Opportunities in Oncology and CNS**

**CRC**-Colorectal Cancer  
**CIPN**-Chemotherapy Induced Peripheral Neuropathy  
**DIPG**-Diffuse Intrinsic Pontine Glioma **DMG**-Diffuse Midline Glioma  
**POC**-Proof of Concept



## Multiple Opportunities for Clinical Benefit

Oxaliplatin (in FOLFOX + Bevacizumab) is considered SOC in 1L mCRC, but many patients cannot tolerate the current regimen

Patients who receive oxaliplatin-based therapy are at heightened risk for treatment-related peripheral neuropathy

75% of patients do not receive full dose of oxaliplatin due to dose reductions and disease progression

There is an unmet need for a new anti-tumor agent which when used in combination with SOC, improves overall survival and quality of life<sup>1,2</sup>

<sup>1</sup>Nakayama G et al. Cancer Chemother Pharmacol . 2014 Apr;73(4):847-55. doi: 10.1007/s00280-014-2416-x. Epub 2014 Feb 28

<sup>2</sup>Zok et al. BMC Cancer . 2021 May 10;21(1):529. doi: 10.1186/s12885-021-08183-y

# Phase 1b/2 Metastatic Colorectal Cancer Study Design



## Study Summary

- ✓ Part 1 site selection; launched 14 of 15 sites
- ✓ Achieved Phase 2 dose – Successful DSMB meeting
- ✓ Internal data cut available under CDA

### Primary Endpoints:

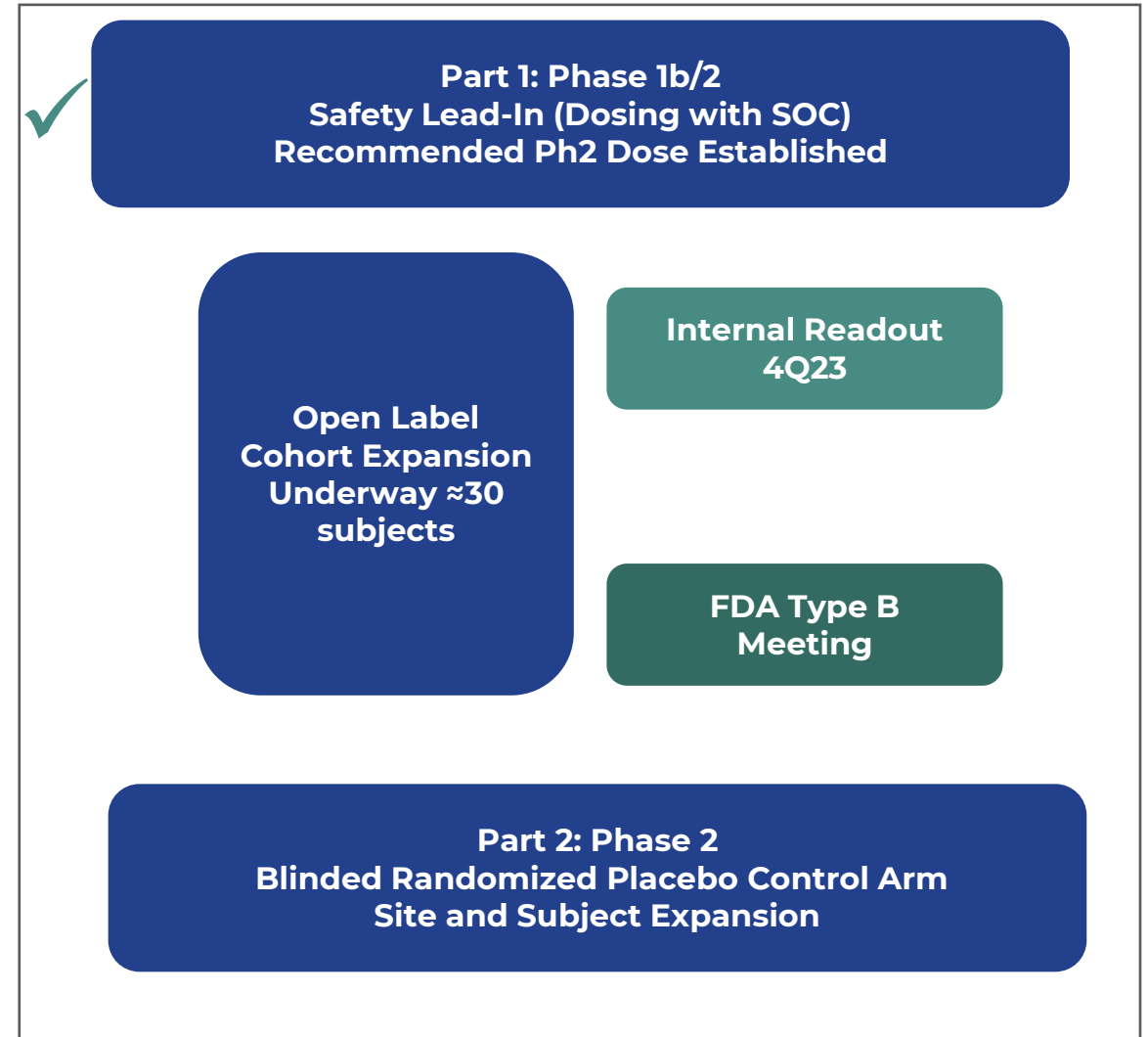
- ORR according to RECIST 1.1 by centralized image assessment
- Total oxaliplatin administered<sup>1</sup>
- Safety

### Secondary Endpoints:

- Overall survival and progression free survival
- Acute Oxaliplatin-induced peripheral neuropathy<sup>2</sup>
- Chronic Oxaliplatin-induced peripheral neuropathy<sup>2</sup>
- PK/PD and Biomarkers

<sup>1</sup> Oxaliplatin dosing is typically reduced or halted in 75% of patients

<sup>2</sup> Patient reported outcome-validated methods





# POC Study – Chemotherapy-induced Peripheral Neuropathy (CIPN) Patients with Chronic CIPN from Prior Cancer Treatments



## Study Summary

### ✓ Study Rationale:

- Potentially disease-modifying:
  - *In vitro* data demonstrate BXQ-350 stimulates nerve cell health & growth, even when followed by cytotoxic agents
  - *In vivo* data show dose-dependent prevention of CIPN phenotype on preclinical mouse model

### ✓ Sizeable market opportunity:

- ~3M Americans suffer from CIPN<sup>1</sup>
- CIPN increases hospitalization, ED, falls, and outpatient visits, costing an estimated \$54B per year in the US<sup>2</sup>
- No approved treatments for CIPN

### ✓ Primary Endpoints:

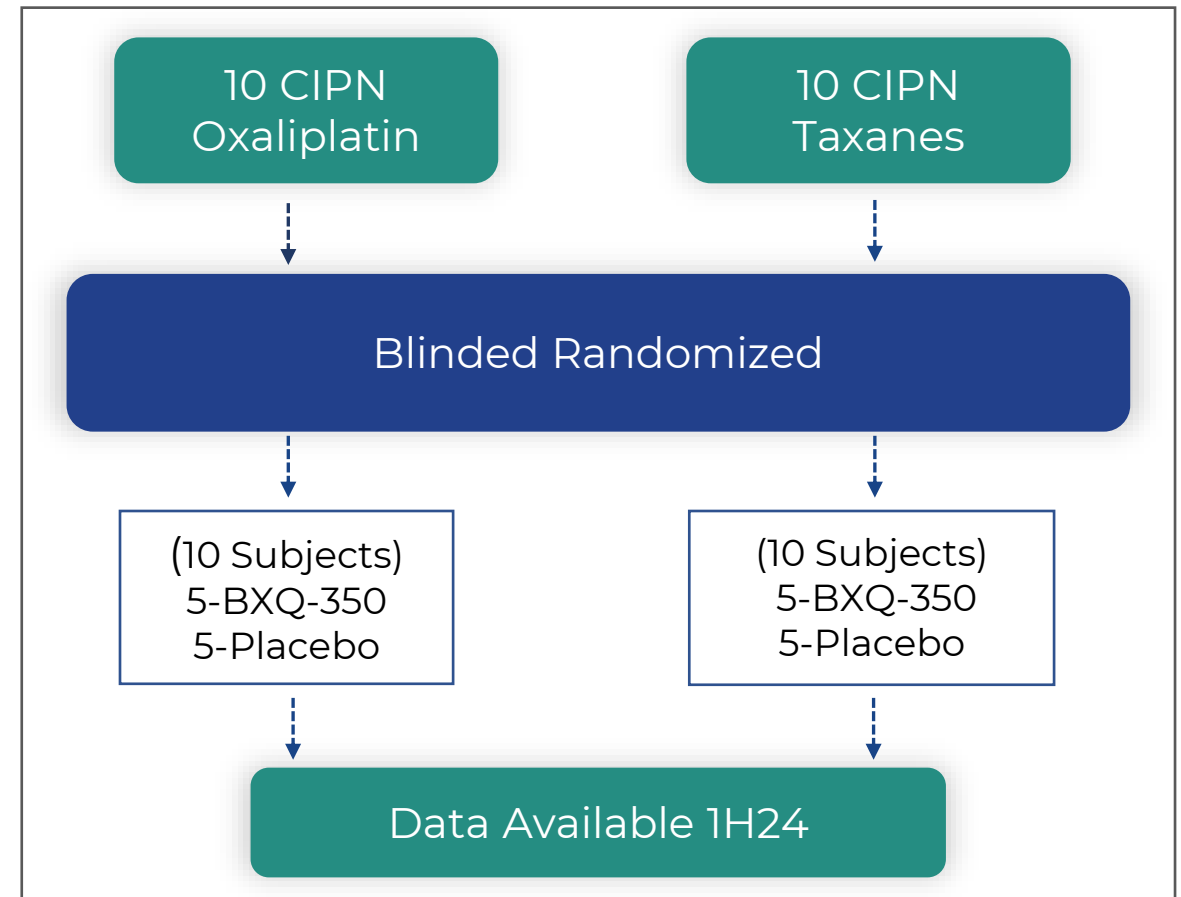
- PK/PD & Biomarkers
- CIPN and QoL Assessment<sup>3</sup>

<sup>1</sup>Foundation for Peripheral Neuropathy

<sup>2</sup>Kerckhove et al., Frontiers in Pharm. 2017

<sup>3</sup>Patient reported outcome-validated methods

## PK/PD PoC CIPN from Oxaliplatin and Taxanes



# Studies enrolling well; Data available under CDA



## Phase 1b/2 mCRC study

### ✓ 21 patients dosed

- 6 month scans available in 10 patients
- No BXQ-350-related DLTs or SAEs
- Open-label data is updated regularly

### ✓ Data available now under CDA:

- Response rate
- Cumulative oxaliplatin dosing

### □ Biomarkers data expected 2Q24

### □ Formal interim readout expected in 3Q24

- 6 month follow-up on 15 patients
- Planned cohort expansion to 30 patients

## CIPN POC Study

### ✓ 13 patients dosed to date

- 8 on placebo, 5 on BXQ-350
- CIPN20 data collected from 2 months to 6 months

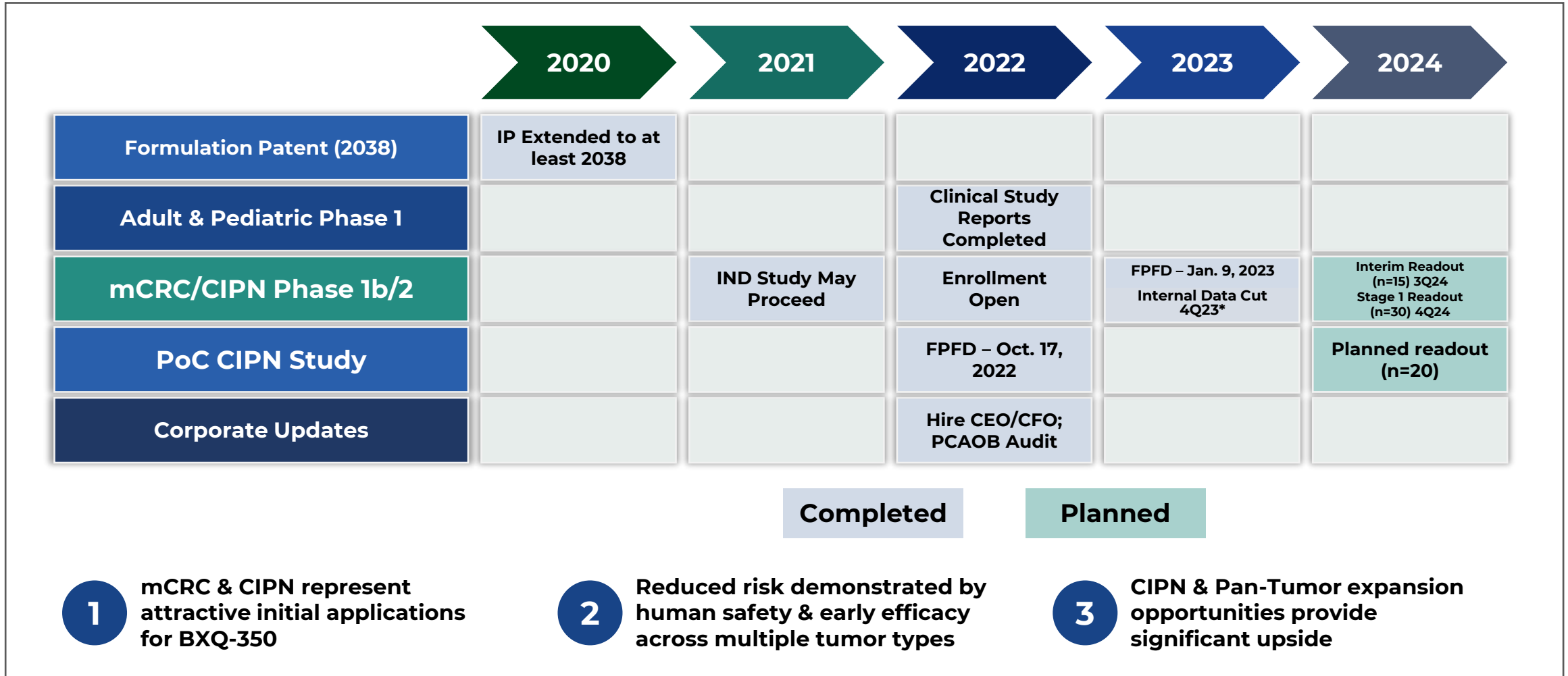
### ✓ All placebo patients have opted to crossover to treatment arm

- Demand despite IV administration

### □ Primary Endpoints:

- PK/PD & Biomarkers including neurofilament lightchain
- CIPN and QoL Assessment
- 20 patient readout expected 2Q24

# Key Catalysts and Milestones



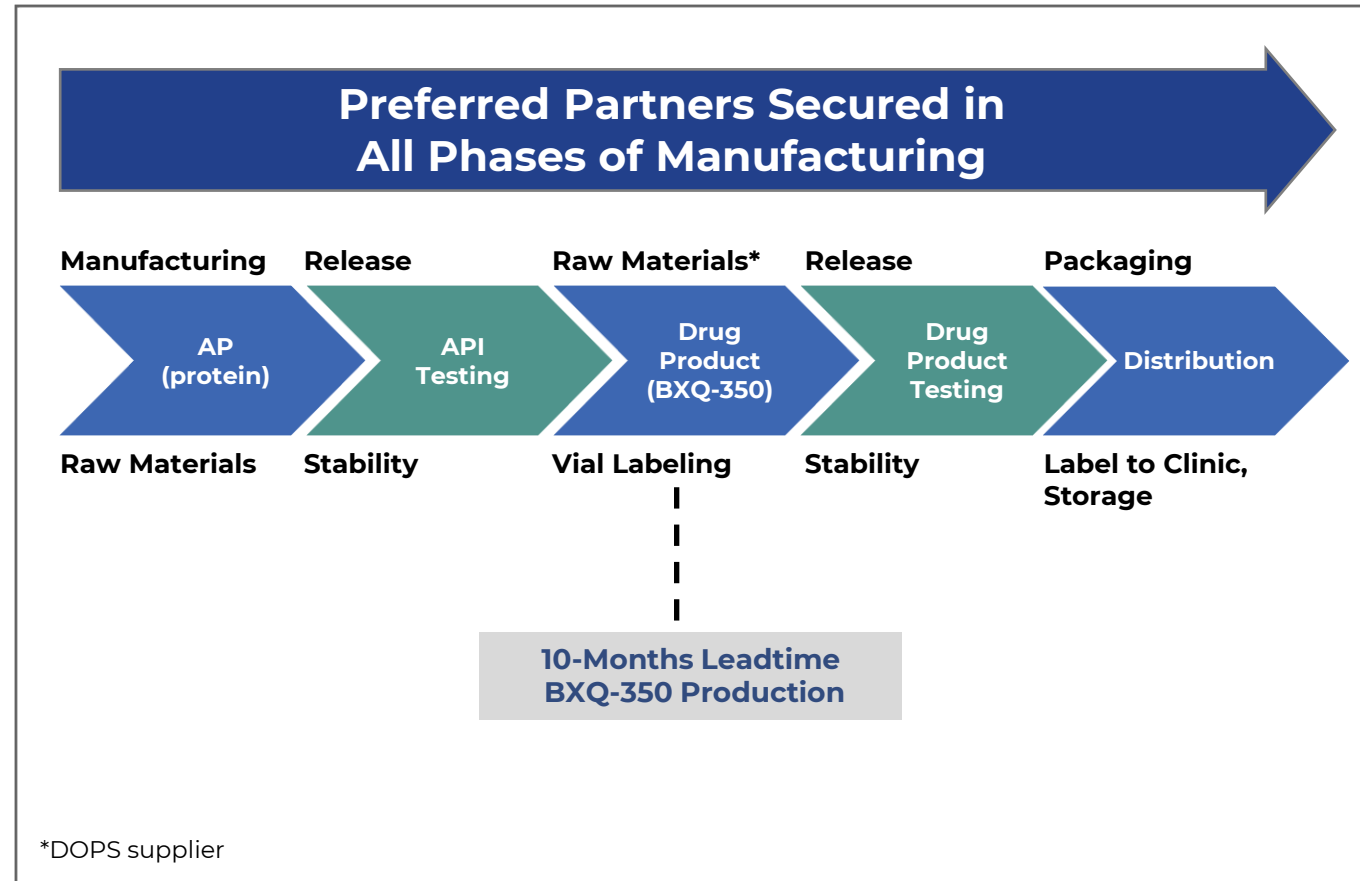
\*Data available under CDA

# Manufacturing is Complex, but Bexion Manufacturing Supply Chain is Well Established



## Key Takeaways

- ✓ FDA compliant for early phase trials and **GMP supplies** on hand for Phase 2 studies
- ✓ **Multiple sites** qualified for Saposin C and for BXQ-350, increasing capacity and scale
- ✓ Significant process improvement work implemented (35% reduction in COGS for Phase 2 2nd campaign)
- ✓ Patented formulation, Trade Secret manufacturing processes
- ✓ Phase 3/Pivotal Readiness plan in place (to include further COGS reduction)



**Bexion has invested \$32 million to date in its manufacturing process**



## Intellectual Property

### Comprehensive, Global Intellectual Property Strategy

- New IP owned by Bexion, including clinical formulation and methods with protection through 2038
- Manufacturing processes currently protected by Trade Secret: purity and process patent applications to be filed upon scale-up/BLA filing
- Additional Potential Future IP: Ongoing Clinical Studies, Methods of Treatment, Biomarkers, Other Formulations
- Eligible for 12 years of biologic market exclusivity for first approved indication

# Significant Indication and Lifecycle Expansion Opportunities



## 1. High Priority, Near-term Indications

Oncology Solid Tumors	Peripheral Neuropathy
Metastatic Colorectal Cancer (mCRC)	Chemotherapy-Induced Peripheral Neuropathy (CIPN)
<b>Supportive Development:</b> Conduct biomarker studies Develop new formulations	

## 2. Medium Priority Indications

Solid Tumors	Pediatric Tumors	Peripheral Neuropathies
GBM, Ependymoma, Appendiceal	DIPG/DMG	Diabetic, idiopathic
<b>Supportive Development:</b> Demonstrate ability to combine with multiple regimens		

## 3. Longer-term, Partner Indications

CNS	Hematology	Other
Parkinson's, Dementia, Gaucher's, Others	Hematological Malignancies	Anti-Viral Auto-Immune

## Investment Summary:

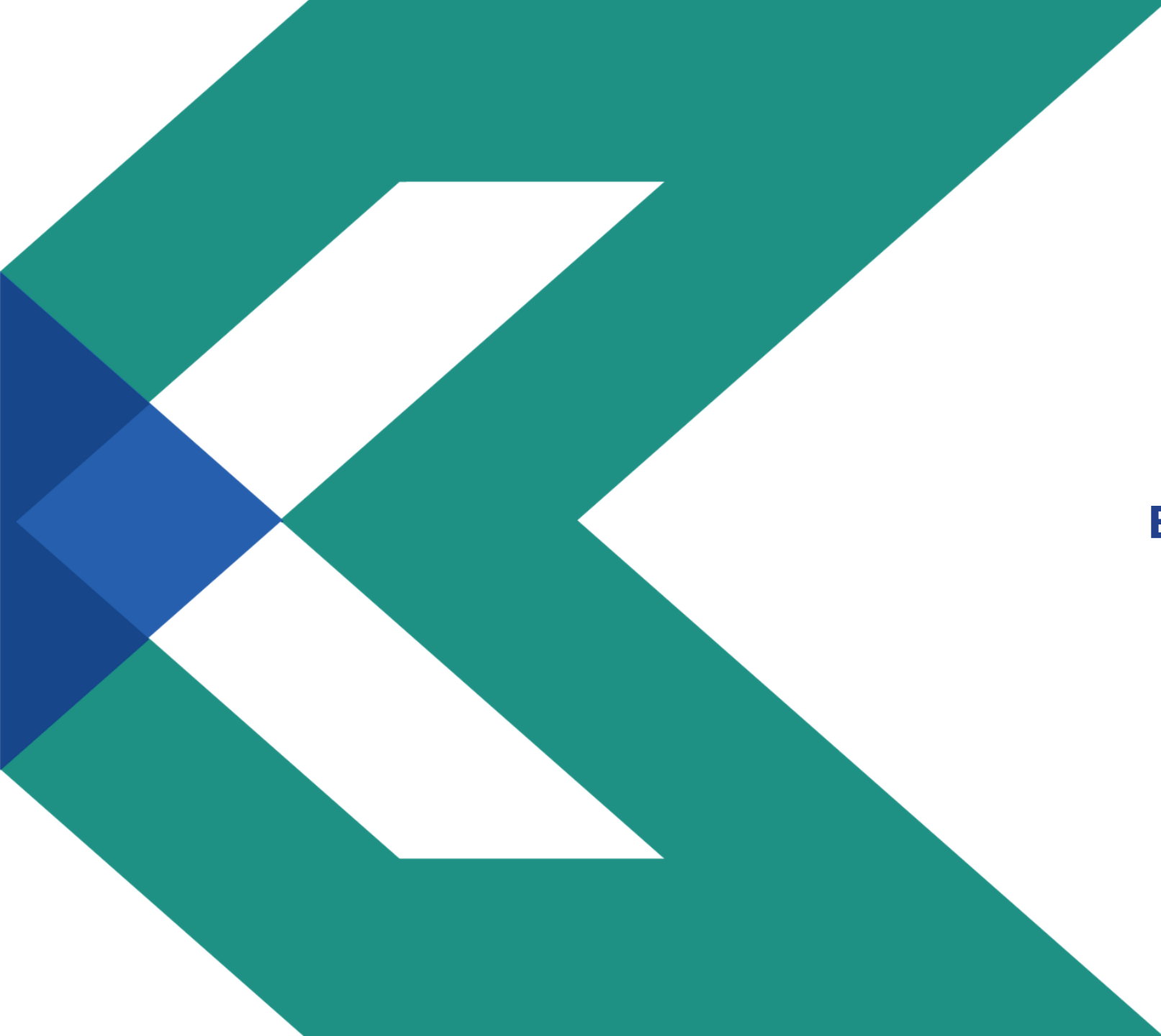
BXQ-350 holds promising therapeutic potential with clinical data becoming available regularly

### Bexion Pharmaceuticals

- **Novel, first-in-class biologic therapy with strong IP position**, under development for solid tumor cancers and Chemotherapy Induced Peripheral Neuropathy (CIPN)
- BXQ-350 is a safe and tolerable compound **in Phase 1b/2 clinical trial for mCRC and a POC trial for Treatment of CIPN**
  - **Clinical data on a rolling basis, with formal readouts this year**
  - **potential significant value milestones**
- Strong, experienced **leadership team**
- CRC and CIPN are each **multibillion-dollar market opportunities**
  - Multiple **sources for growth** in oncology and other indications such as neuropathy and CNS indications
- Completing \$50M Series C at a \$175M pre-money valuation
- Will seek \$80M in a Series D financing in 2024, post data-readouts
- IPO under consideration following Series D, pending market dynamics



*Data available on an ongoing basis to interested parties under CDA*



# Backups



# CONFIDENTIAL – Risk Factor Disclaimers



## **Our business is subject to numerous risks and uncertainties that prospective investors should consider before investing in our company. These risks include, but are not limited to, the following:**

- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We need to raise additional capital to continue our operations, initiate clinical trials and to implement our business plan.
- If we are unable to successfully raise sufficient capital, our future clinical trials and product development could be limited, and our long-term viability may be threatened. Investors may experience future dilution as a result of future equity offerings.
- We rely upon third parties to conduct our clinical trials. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to meet deadlines for completion of such trials, or obtain or maintain marketing approval for BXQ-350, and our business could be substantially harmed.
- A breach of our information technology systems or cybersecurity precautions could subject us to liability or interrupt the operation of our business..
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of BXQ-350.
- If BXQ-350 produces undesirable side effects and serious reactions or events, we may be required to delay further clinical development or the FDA may halt our trials.
- The outcome of clinical trials may not be predictive of the success of later clinical trials as interim results of a clinical trial do not necessarily predict final results; the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.
- We contract with two manufacturers for the manufacture of our product candidates and expect to continue to do so for commercialization, if allowed to proceed. This reliance on these manufacturers increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations and the financial condition of the third parties on which we rely.
- If we are unable to obtain, or if there are delays in obtaining, required approval from the applicable regulatory agencies, we will not be able to commercialize our product candidate and our ability to generate revenue will be materially impaired.
- The FDA's and other comparable regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate, which would negatively impact our business.
- If we are unable to protect or enforce our intellectual property, we may be unable to prevent third parties from using our intellectual property. Our business could suffer, and intellectual property rights don't necessarily address all potential threats
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.



**Thank You**