

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 8-K
CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 13, 2020**

CHANTICLEER HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35570

(Commission
File Number)

20-2932652

(IRS Employer
Identification No.)

**7621 Little Avenue, Suite 414
Charlotte, North Carolina 28226**
(Address of principal executive offices)

Registrant's telephone number, including area code: **(704) 366-5122**

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 Par Value	BURG	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On January 13, 2020, representatives of Sonnet BioTherapeutics, Inc., a New Jersey corporation (“Sonnet”) began making presentations to investors using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1 (the “Investor Presentation”) and incorporated herein by reference. Sonnet expects to use the Investor Presentation, in whole or in part, in connection with presentations to investors, analysts and others during the fiscal year ending December 31, 2020.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

99.1 [Sonnet BioTherapeutics, Inc. Investor Presentation dated January 13, 2020.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned duly authorized.

Chanticleer Holdings, Inc.,
a Delaware corporation
(Registrant)

Date: January 13, 2020

By: /s/ Michael D. Pruitt
Name: Michael D. Pruitt
Title: Chief Executive Officer



Corporate Presentation
January 2020

This presentation contains forward looking statements that do not guarantee future performance

Forward Looking Statements

This presentation contains forward-looking statements about Sonnet BioTherapeutics based on management's current expectations which are subject to known and unknown uncertainties and risks. Words such as "anticipated," "initiate," "expect," "intend," "plan," "believe," "seek," "estimate," "may," and variations of these words or similar expressions are intended to identify forward-looking statements. Our actual results could differ materially from those discussed due to a number of factors, including, but not limited to, our ability to raise additional equity and debt financing on favorable terms, the success of our R&D programs, our ability to obtain regulatory approval of our clinical assets and other risk factors.

We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. Unless the context requires otherwise, references to "Sonnet," "Company," "we," "us" and "our" refer to Sonnet BioTherapeutics.

Corporate Background

- Incorporated in New Jersey
 - Headquarters: Princeton, New Jersey
 - Other Locations: New York City, Geneva
- Employees, Consultants and Contracted Scientists/Experts: Approximately 30 people
- Internal Pipeline Focus: Oncology
 - Proprietary technology platform
 - Existing licensing/partnership interest from large multinational pharmaceutical companies
 - External business development opportunities also exist outside oncology
- Recent acquisition of clinical-stage asset, SON-080, for \$33 million
 - Clinical efficacy studies in Chemotherapy-Induced Peripheral Neuropathy (CIPN) to commence during 2020
- Capital invested into Sonnet since inception: Approximately \$30 million

Corporate Highlights

Sonnet is a clinical stage biopharmaceutical company with a proprietary, modular biologic drug development platform

We have a deep knowledge of cytokine biology, complemented by extensive drug discovery and development expertise

Our corporate strategy comprises an internal therapeutic pipeline of oncology candidates, with external business development initiatives underway across oncology, autoimmune and inflammatory diseases

Lead drug, SON-080, is a low dose, recombinant formulation of human IL-6 scheduled to enter pilot efficacy studies in patients with chemotherapy induced peripheral neuropathy (CIPN) during 2020

Our Fully Human Albumin Binding (F_HAB) platform has identified multiple candidates for development. Key attributes of the technology include:

- Compatibility with many biologic drug classes, including interleukins, growth factors, peptides and vaccines
- Extended pK
- Targeted delivery
- Increased *in vivo* efficacy
- Single- or bi-specific mechanism of action

Our three-pronged business approach is focused on:

- **Asset - Licensing**
 - Pipeline partnering
 - Non-dilutive funding
 - Funding to develop other assets
- **Platform - M&A**
 - 4-5 assets in clinic
 - 4-5 preclinical assets
 - Expand platform beyond oncology
- **Proprietary Pipeline Development**

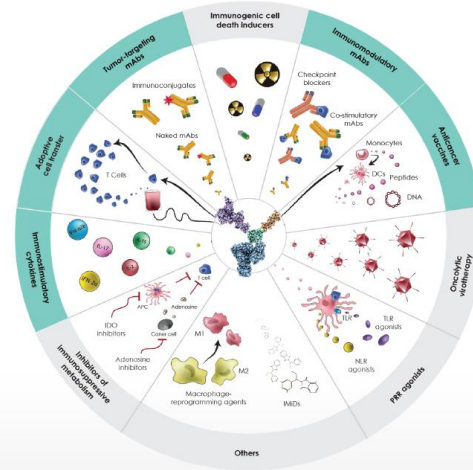
The Sonnet Platform

Asset generation capabilities across major biologic drug classes

Five Filed Patent Applications

F_HAB construct design for numerous targets:

- Immunotherapy - Combination with checkpoint inhibitors
- Drug conjugation
- Vaccine
- Bone/Tissue Metastasis
- CAR-T



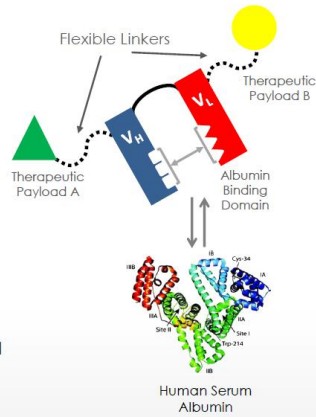
The Sonnet Technology Advantage

Sonnet's Fully Human Albumin Binding (F_H AB) technology utilizes a single chain antibody fragment (scFv) capable of delivering one or two active drug compounds

- Therapeutic payloads attached via **flexible linker peptides**

Following administration, Sonnet's F_H AB-derived candidates **bind to and "hitch-hike" on endogenous human serum albumin (HSA)** for transport to target tissues

- F_H AB has been designed to **bind, unbind and rebind to albumin** in an on-and-off fashion through a physical bonding mechanism, obviating the need for chemical conjugation



KEY FEATURES

Fully Human Construct

- Low/No immunogenicity
- Single- or Bi-specific design

Targeted Delivery

- High efficacy
- Low side effects

Enhanced pK

- Extended dosing intervals

Small Size with Linear Flexibility

- Optimized tumor penetration

Mammalian Cell Production (CHO)

- Glycosylated

Modular

- Off-the-shelf system
- Rapid asset development

Pipeline Overview

First wave pipeline will target IL-6, IL-12, IL-15, IL-18, GMcSF and TGF β

	Program	Indications	Discovery	Pre-Clinical	Phase I	Next Milestone:
F ₁ AB Platform	SON-080 (low dose IL-6)	Chemotherapy Induced Peripheral Neuropathy*				Pilot Efficacy Study Initiation
	SON-1010 (IL12-F ₁ AB)	Undisclosed Solid Tumor				GLP Tox
	SON-1210 (IL15-F ₁ AB-IL12)	Undisclosed Solid Tumor				Non-GLP Tox
	SON-2014 (GMcSF-F ₁ AB-IL18)	Early Stage Cancer				Preclinical Efficacy
	SON-3015 (Anti-IL6-F ₁ AB-Anti-TGF β)	Tumor and Bone Metastases				Preclinical Efficacy

*Potential to expand development into diabetic neuropathy

IL-6: A Disease Modifier of CIPN

CIPN Patient Population¹

- >50% of cancer patients receiving chemotherapy develop CIPN
- CIPN peak prevalence as high as 70%
- New cases under chemotherapy in the US ~ 10 million
- US cancer survivor population ~ 17 million
- CIPN represents a significant commercial opportunity

Symptoms Include

- Spontaneous Pain Sensation – itching, burning, tingling
- Motor Weakness – grasping, walking, balance impairment
- Loss of sensory perception at the extremities – numbness
- Autonomous nervous system impairment – bladder, stomach, cardio vascular

Current Standard of Care

- Pain relievers, including Cymbalta, opioids
- Limited efficacy, high side effect burden
- No disease modifying treatments currently exist

Data supporting neurotrophic properties in various disease models

- Dubový P et al. Cell Biol. 2019
- Yang P et al. PLoS One. 2015
- Leibinger M et al. Cell Death Dis. 2013
- Yang P et al. Exp Neurol. 2012

Key Data Summary:

- ✓ **Neuroprotection**
 - *In vitro* and preclinical data
- ✓ **Axonal Growth**
 - Preclinical data
- ✓ **Safety at Low Dose**
 - Preclinical data
 - Phase 1 data

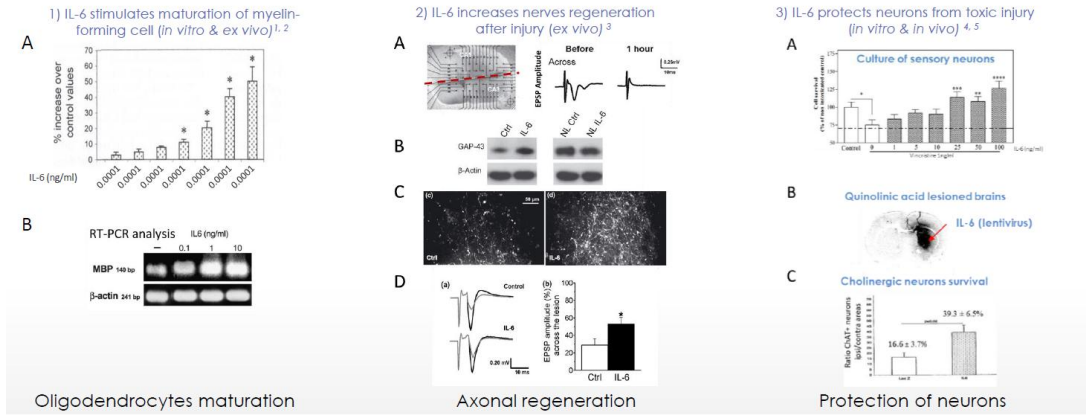


¹<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6368751/>
²<https://cancercontrol.cancer.gov/ocs/statistics/statistics.html>
³[https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(19\)30163-9/fulltext?dgcid=raven_jbs_etoc_email](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(19)30163-9/fulltext?dgcid=raven_jbs_etoc_email)

Neuroprotection by IL-6

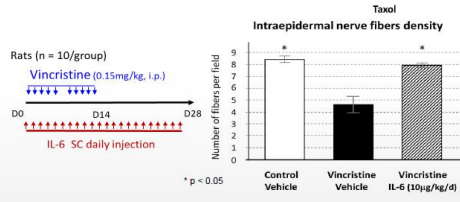
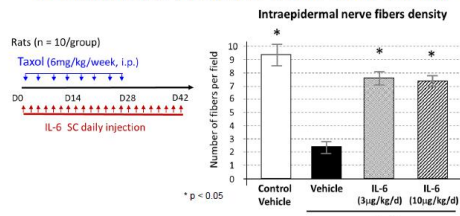
In vitro, *ex vivo* and *in vivo* data validate the neuroprotective activity

¹Valério et al., 2002; ²Pizzi et al., 2004;
³Hakkoum et al., 2007; ⁴Neurofit, 2003;
⁵Bensadoun et al., 2001

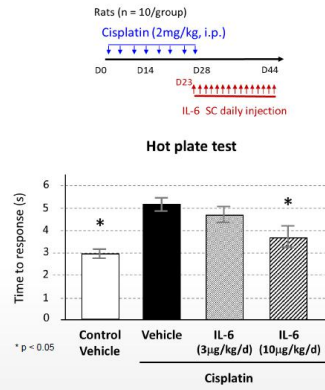


IL-6 Intrinsically Reactivates Axonal Growth

IL-6 maintains / restores nerve fiber density



IL-6 restores sensation



IL-6 is safe and well tolerated at the target dose

Phase I/II clinical data

- Condition: Thrombocytopenia
- Patients: n=213; all types also including Grade III/IV cancer¹
- Studies: 10 independent Phase I/II studies²
- Co-treatment: Diverse antineoplastic therapies³
- Doses : 0.25-32 µg/kg/day, or 5-20 µg/kg/TIW⁴ subcu
- Duration: Up to 10 weeks
- pK parameters: $T_{1/2}$: 4-5h, $C_{max(0.5\mu\text{g/kg})}$: 85pg/mL blood
- Side effect profile: Similar AEs and SAEs to controls, eg fever and rigor, headache, vomiting (at target dose range).
- No exacerbation of pain or neuropathy were observed after IL-6 administration.
- Safety window: MTD=5µg/kg/day or 10µg/kg/TIW
- Doses below 2.5 mg/kg/day were well tolerated
- Sonnet target dose will be 0.2 – 0.8 mg/kg/TIW, 50 times below estimated MTD.

Safety of low dose IL-6 independently, externally verified

IL-6: Plan for Proof-of-Efficacy in CIPN Patients

Low dose, recombinant human IL-6 is safe in cancer patients

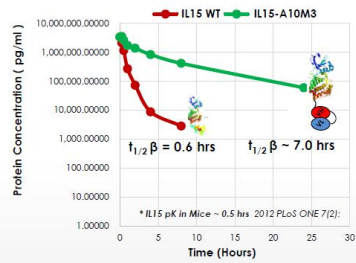
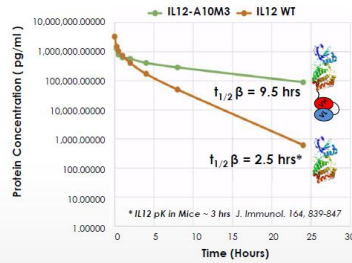
Design of a randomized, double-blind, placebo-controlled trial is currently underway:

- Cancer survivors with at least 6-12 months of CIPN post-antineoplastic treatment
- 2-3 doses, subcutaneously delivered by a home healthcare professional
- Treatment duration, 6-12 weeks
- Endpoints
 - Intra-epidermal nerve fibre density (nerve preservation)
 - Patient assessment questionnaire

F_HAB Constructs IL-12 and IL-15: Pharmacokinetic Half Life

The aim of this study was to demonstrate in mice, the pharmacokinetic (pK) behavior of naked IL-12 and IL-15 compared to the same interleukins linked to Sonnet's F_HAB domain

Method: 8 mice C57B/TP, Age 9.5 weeks dose IV, sacrificed @ 5, 15, 30 mins, 1, 2, 4, 8, 24 & 48 hrs. Serum tested by ELISA



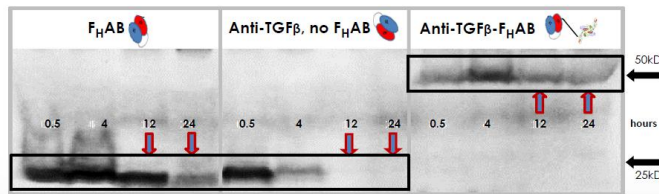
Fusion to F_HAB increased the plasma half-life of IL-12 > 4x and IL-15 >10X

IL-12 MW = 70kd vs IL-15 MW=13kd

anti-TGF β and anti-TGF β -F_HAB: Evaluating Tumor Accumulation

An *in vivo* Demonstration of F_HAB Proof-of-Concept

Western blot analysis of Mouse 4T1 (TGF β -positive) tumor (~150mm³) extracts from mice terminated at 0.5, 4, 12 and 24-hours post IV injection with 100 ug/mouse of F_HAB, anti-TGF β (4D9M) and anti-TGF β (4D9M)-F_HAB.



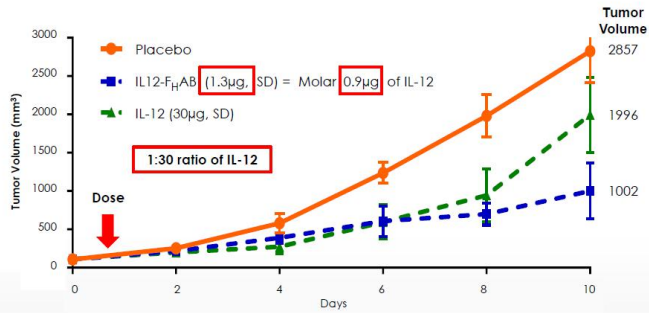
Results show an accumulation and retention of F_HAB in the tumor

- F_HAB - Present at 0.5 hours, peaks at 4 hours and detectable through 24 hours.
- Anti-TGF β - Present at 0.5 hours then declines at 4 hours and undetectable at 12 and 24 hours.
- Anti-TGF β -F_HAB - Present at 0.5 hours, and detectable through 24 hours.
- F_HAB accumulates in the tumors 24 hrs+ and without F_HAB, the scFv enters the tumor but diffuses out after 4 hrs.

Data supports F_HAB POC for the platform's ability to enhance penetration, accumulation and retention within the tumor.

IL12-F_HAB vs IL-12: Tumor Reduction Data

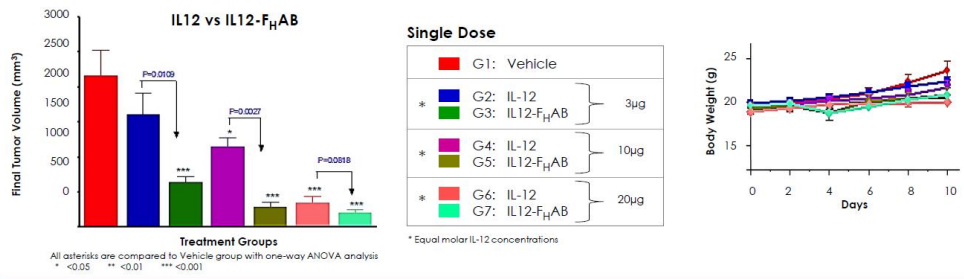
Evaluation of Single Dose (SD) IL12-F_HAB (1.3μg) vs IL-12 (30μg) in B16F10 Melanoma (established @100 mm³, n=8)



IL-12 (1μg) and IL12-F_HAB (1.3μg) are molar equivalent and have similar bioactivity, *in vitro*; however, *in vivo*, F_HAB is approximately 30-fold more potent than IL-12 (at day 10, 1.3μg IL12-F_HAB > IL-12 30μg).

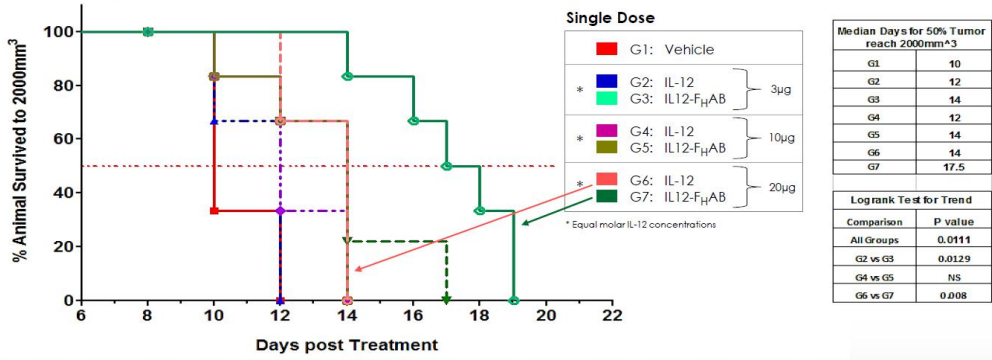
IL12-F_HAB vs IL-12: Dose Level Comparisons

Tumor Volume Changes Between Groups on Day 10 Post Treatment (Day 0 @ 100 mm³)



Analysis of tumor volumes shows dose dependent decreases in tumors in both IL12- and IL12-F_HAB-treated mice, as compared to vehicle control. IL12-F_HAB-treated mice showed large, statistically significant, decreases in tumor volumes when analyzed against equimolar-dosed, IL12-treated mice. Results show IL-12 anti-tumor activity is markedly enhanced with the extension of t_{1/2} by F_HAB.

IL12-F_HAB vs IL-12: Survival Data



Kaplan-Meier evaluation of mouse B16F tumor survivability shows a marked increase in survival with IL12-F_HAB treatment. Doses of 10µg and 20µg of IL-12 WT exhibited 50% survival at 2 and 4 days over vehicle control (10 days). All doses of IL12-F_HAB showed 50% survival over vehicle at 14 and 17.5 days. Survivability at the lowest doses of IL12-F_HAB were equivalent to highest dose IL-12 WT.

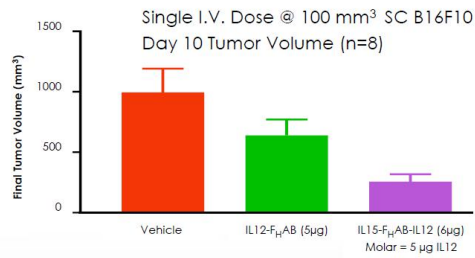
IL15-F_HAB-IL12 vs IL12-F_HAB

Sonnet Bi-Specific Construct IL15-F_HAB-IL12

Synergistic Biologic Activity:

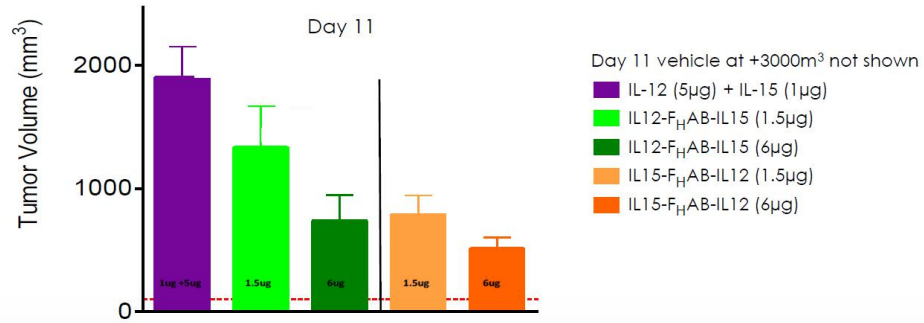
IL-12: ↑ IL-15 alpha receptor, ↑ IFN,
↑ NK/T cells, ↑ TH1 and ↓ T reg

IL-15: ↑ IL-12 beta 1 receptor, ↑ NK
cells, ↓ CD8 memory loss by
apoptosis



IL15-F_HAB-IL12 produced a greater reduction in tumor volume than the molar equivalent dose of IL12-F_HAB.
In vivo, IL15-F_HAB-IL12 is efficacious in reducing tumor growth.

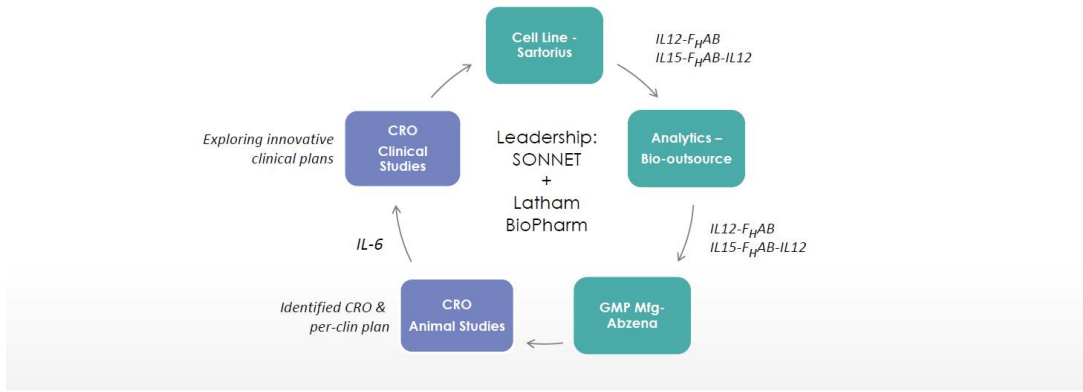
IL15-F_HAB-IL12 vs Concomitant IL-12 and IL-15



IL15-F_HAB-IL12 shows better reduction than IL12-F_HAB-IL15 or free, concomitantly dosed IL-12 and IL-15

Execution Efficiency

Integrating a Best-in-Class Platform with a World-Class Development Strategy



Leadership

Accomplished management team with deep experience in biotechnology



Pankaj Mohan, PhD
Founder, CEO & Chairman

Biotechnology entrepreneur with start-up, academic, large biopharma and government experience.

Founded Oncobiologics in 2011 and led it to a successful IPO in 2016 (Nasdaq: OHS).

More than 20 years in key technical and business roles at Genentech, Eli Lilly and Bristol-Myers Squibb.

Served as an Assistant Professor at University College London, and author of an industry reference book on bioprocess operations (McGraw-Hill).



Jay Cross
Chief Financial Officer & Chief Business Officer

Over 19 years successfully advising, financing and investing in the biotechnology sector.

Former Managing Director, Healthcare Investment Banking, Chardon, and Senior Analyst and Portfolio Manager of Biotech Asset Management, Citadel and SAC Capital. Previously on the healthcare equity research teams at Goldman Sachs and Hambrecht & Quist.



John Cini, PhD
Chief Scientific Officer /Co-Founder

Former Vice President of Discovery and Development Sciences at Oncobiologics.

Successfully advanced more than 30 novel monoclonal antibody products from discovery to IND.

Several novel products and formulation patents and applications related to wound healing & cancer therapy.

Medarex - Executive Director from 1999-2009 (acquired by BMS), Principal Scientist at Johnson & Johnson and Bayer Pharmaceuticals.



Terence Rugg, MD
Chief Medical Officer

Internationally respected oncologist with nearly 30 years experience in the development of oncology drugs. Involved in the development of over 30 therapeutic compounds, including at least 12 different classes of anti-cancer drugs.

Formerly Vice President, BioOncology Medical Affairs at Genentech, Chief Medical Officer and VP-Development for SGX Pharmaceuticals, Vice President and Head of Oncology/Medical Affairs at Sanofi-Aventis and Head of Oncology for Aventis Global Medical Affairs.

Previous positions at Eli Lilly, Zeneca Pharmaceuticals, Ilx Oncology and British Biotech.



Susan Dexter
Chief Technical Officer

Over 25 years in biotechnology science, manufacturing and business development. Ms. Dexter has worked as a scientist doing cell culture and small scale manufacturing.

Management of biotechnology contract manufacturing services ranging from process development through commercial manufacturing, and strategic consulting-related services.

Roles include Managing Director, Latham Biopharm Group, Chief Business Officer at Xcellerex, Inc., VP of Business Development at The Dow Chemical Company, Assoc. Director of Business Development, Celltech and Lonza.

