
**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): **October 16, 2019**

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 October 16, 2019, 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, 2019.

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 October 16, 2019.](#)

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: October 16, 2019

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



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**

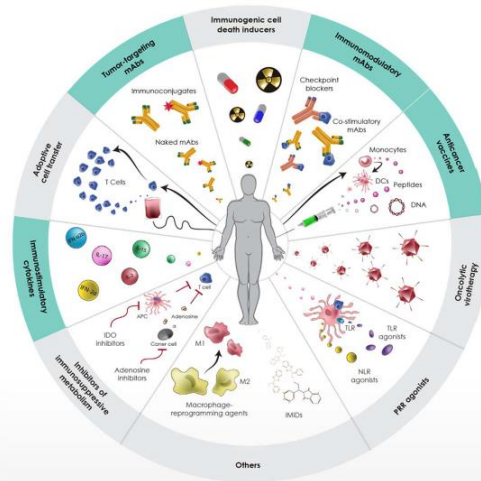
Strategic Investment Partner Secured

Global Emerging Markets (GEM) is a multibillion dollar investment group with an established interest in Sonnet's success

- In August 2019, through a share exchange agreement with Relief Therapeutics Holding SA (SIX: RLF), Sonnet acquired the rights to develop low-dose Interleukin-6 (IL-6, SON-080)
 - This transaction valued Sonnet at \$200 million and valued the Relief asset at \$33 million
 - Relief currently owns 13.75% of Sonnet's common shares
- GEM is the largest shareholder of Relief with approximately 30% ownership
- GEM is providing Sonnet access to up to \$100 million through a common stock purchase facility, available to Sonnet at timing intervals and in amounts, as dictated by Sonnet, when listed
 - Interests are substantially aligned to support Sonnet's pipeline
 - No fees or warrants
- The funding agreement is designed to provide a long-term backstop and financing stability for Sonnet's operations

The Sonnet Platform

Asset generation capabilities across major biologic drug classes



Pipeline Overview

First wave pipeline will target IL-6, IL-12, IL-15, IL-18, GMCSF and TGFβ

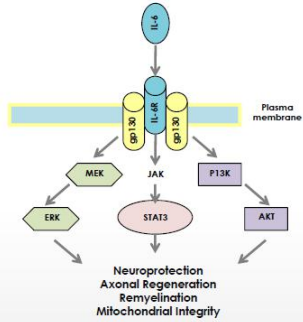
| | Program | Indications | Discovery | Pre-Clinical | Phase I | Next Milestone: |
|--|---|---|-----------|--------------|---------|---------------------------------|
| F _H A _B Platform | SON-080 (low dose IL-6) | Chemotherapy Induced Peripheral Neuropathy* | | | | Pilot Efficacy Study Initiation |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

*Potential to expand development into diabetic neuropathy

IL-6: A Disease Modifier of CIPN

CIPN is a degeneration of nerve fibers resulting from chemotherapy

In peripheral neurons, IL-6 triggers a series of pathways for the maintenance of mitochondrial function and axonal regeneration.



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
- Autonomus 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

SON-080: Clinical History

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

In Phase I studies comprising 214 total cancer patients:

- SC delivery of IL-6 doses dependently increases plasmatic IL-6, with plasmatic $t_{1/2}$ ~ 4 hours
- In none of the trials was exacerbation of tumour burden observed
- In several patients, IL-6 treatment induced partial cancer remission or disease stabilization
- Adverse events mostly observed following intravenous, not subcutaneous administration
- Human MTD at $3\mu\text{g}/\text{kg}/\text{day}$ or $10\mu\text{g}/\text{kg}/3\text{x Weekly}$ (TIW)

In cancer patients, low-dose IL-6 was very well tolerated

| Dose | Administration | Side Effects | SAE | Comment |
|--|------------------------|--|----------|------------------------|
| $<1\mu\text{g}/\text{kg}/\text{Daily}$ | Subcutaneous injection | Fever, chills, anemia | Headache | |
| $<1\mu\text{g}/\text{kg}/3\text{x Weekly}$ | Subcutaneous injection | Low level fever, chills, anemia (none requiring treatment) | None | Selected dose for CIPN |

Target dose for neuropathies of $0.2\mu\text{g}/\text{kg}/\text{EOD}$ gives a large safety margin of 50x

The Sonnet Technology Advantage

Sonnet's Fully Human Albumin Binding (F_{HAB}) technology utilizes a single chain antibody fragment (scFv) capable of delivering one or two active biologic compounds

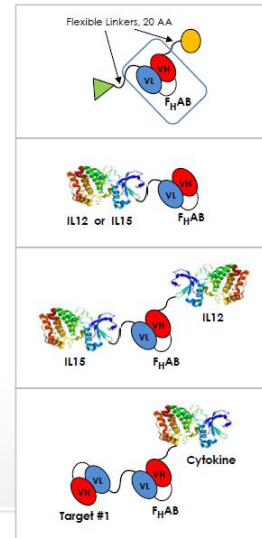
- Therapeutic payloads attached via flexible linker peptides

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

- F_{HAB} has been designed to bind, unbind and rebind to albumin in an on-and-off fashion, obviating the need for chemical conjugation

Sonnet's F_{HAB} is the foundation of **a modular, plug-and-play drug development platform** with several distinct advantages:

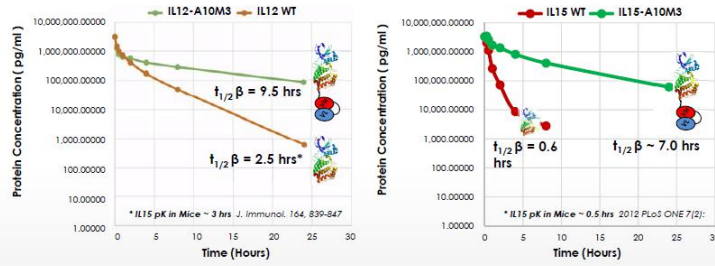
- Fully human construct produced in mammalian cell culture (CHO)
- Targeted, directed activity for tumor selectivity
- Extended pK
- Single- or bi-specific mechanism of action
- Increased *in vivo* efficacy observed
- Technology can be paired with many biologic drug classes, including cytokines, antibodies, peptides and vaccines, across multiple disease areas



pK t_{1/2} of F_HAB Constructs IL-12 and IL-15

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 fusion proteins 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



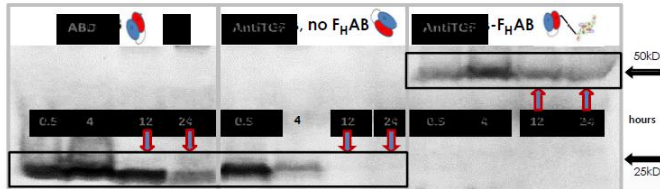
Fusion to F_HAB increased the plasma half-life of IL-12 > 4x and IL-15 >10X

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

Evaluating anti-TGF β and anti-TGF β -F_HAB 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.



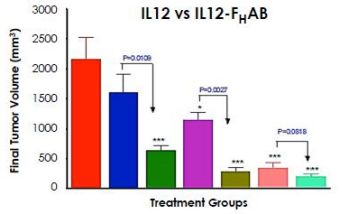
Results show an accumulation and retention of F_HAB in the tumor

- 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

Comparison of Tumor Volumes Between Groups on Day 10 Post Treatment (Day 0 @ 100 mm³)

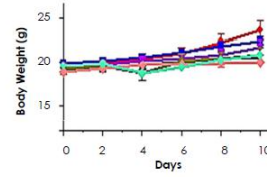


All asterisks are compared to Vehicle group with one-way ANOVA analysis
 * <0.05 ** <0.01 *** <0.001

Single Dose

| | | |
|---|------------------------------|------|
| ■ | G1: Vehicle | |
| ■ | * G2: IL-12 | 3µg |
| ■ | * G3: IL12-F _H AB | |
| ■ | * G4: IL-12 | 10µg |
| ■ | * G5: IL12-F _H AB | |
| ■ | * G6: IL-12 | 20µg |
| ■ | * G7: IL12-F _H AB | |

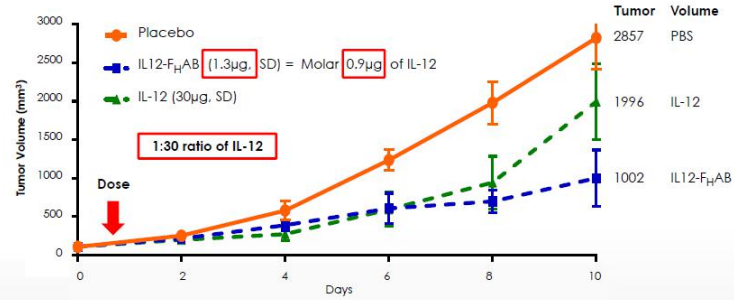
* Equal molar IL12 concentration



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 ½ by F_HAB.

IL12-F_HAB vs IL-12

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).

IL15-F_HAB-IL12

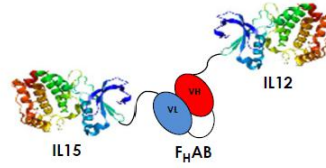
Efficacy in Melanoma Mouse Model

Enhanced Reciprocal Biologic Activity:

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

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

IL-12 activates T cells and increases CD8 number, hence Sonnet's IL15-F_HAB-IL12 should be more effective than IL-15 alone.



Summary:

- *In vivo*, IL15-F_HAB-IL12 > IL12-F_HAB-IL15 > IL-12 + IL-15 efficacious in reducing tumor growth
- First-of-its-kind bi-specific interleukin F_HAB construct shows significant synergy with two interleukins

IL15-F_HAB-IL12 vs IL12-F_HAB

Single I.V. Dose @ 100 mm³ SC B16F10

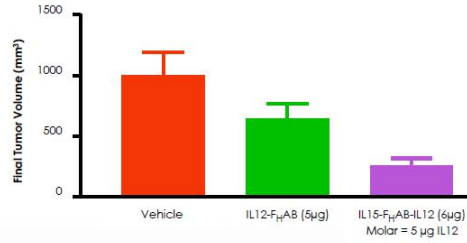
Day 10 Tumor Volume (n=8)

Sonnet Bi-Specific Construct IL15-F_HAB-IL12

Synergistic Biologic Activity:

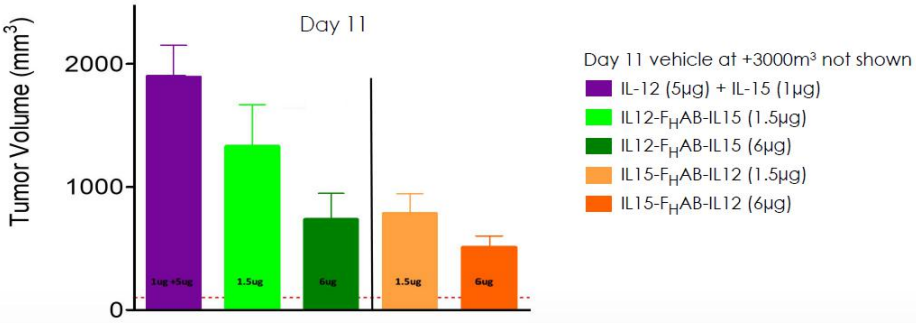
IL-12: ↑ IL-15 alpha receptor, IFN, NK/T cells, TH1 and ↓ T reg

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



IL15-F_HAB-IL12 produced a greater reduction in tumor volume than the molar equivalent dose of IL12-F_HAB

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

Business Strategy

A Three-Pronged Approach

Asset - Licensing

- Pipeline partnering
- Non-dilutive funding
- Funding to develop other assets

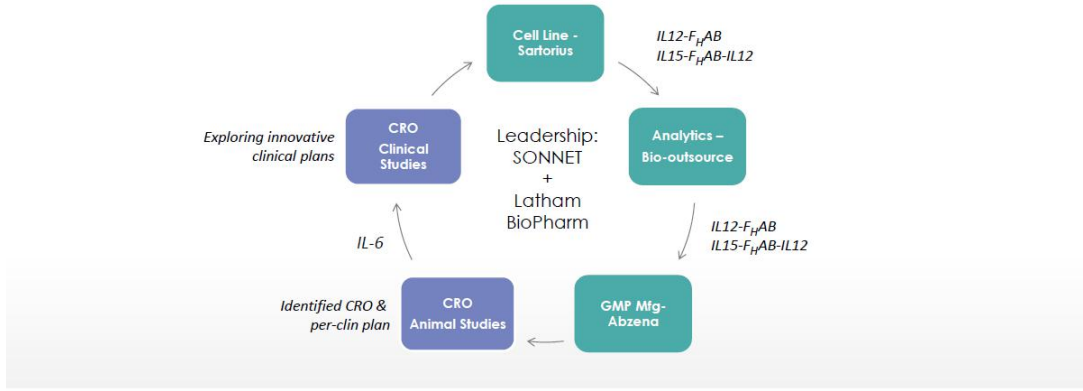
Platform - M&A

- 4-5 assets in clinic
- 4-5 preclinical assets
- Expand technology beyond oncology

Proprietary Pipeline Development

Execution Efficiency

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



Comparable Companies

Select Oncology IPOs, '18/'19

| Company Name | Ticker Symbol | IPO Date | Therapeutic Modality | Lead Asset Stage at IPO | Pre-Money Mkt Cap (\$M)* | Current Stage of Most Advanced Asset | Current Mkt Cap (\$M)** |
|----------------------------|---------------|-----------|--------------------------------------|-------------------------|--------------------------|--------------------------------------|-------------------------|
| Aprea Therapeutics | APRE | 10/3/2019 | Targeted small molecules | P1/2 | 213 | P1/2 | 401 |
| IGM Biosciences | IGMS | 9/18/2019 | Biologics | Preclinical | 267 | Preclinical | 579 |
| Atreca | BCEL | 6/20/2019 | Biologics | Preclinical | 230 | Preclinical | 300 |
| Bicycle Therapeutics | BCYC | 5/23/2019 | Biologics | P1/2 | 192 | P1/2 | 171 |
| IDEAYA Biosciences | IDYA | 5/22/2019 | Targeted small molecules | P1 | 145 | P1 | 131 |
| NextCure, Inc | NXTC | 5/8/2019 | Biologics | P1/2 | 243 | P1/2 | 616 |
| Turning Point Therapeutics | TPX | 4/17/2019 | Targeted small molecules | P1 | 367 | P1 | 1301 |
| TCR2 Therapeutics | TCRR | 2/13/2019 | Biologics | P1 | 273 | P1 | 361 |
| Harpoon Biosciences | HARP | 2/7/2019 | Biologics | P1 | 259 | P1 | 324 |
| Gritstone Oncology | GRTS | 9/27/2018 | Biologics | Preclinical | 330 | P1 | 307 |
| Arvinas, Inc | ARVN | 9/26/2018 | Targeted small molecules | Preclinical | 409 | P3 | 564 |
| Sutro Biopharma | SIRO | 9/26/2018 | Biologics | P1 | 257 | P1 | 216 |
| Neon Therapeutics | NTGN | 6/29/2018 | Biologics | P1 | 351 | P1 | 60 |
| Autolus Therapeutics | AUTL | 6/21/2018 | Biologics | P1 | 509 | P1/2 | 546 |
| Surface Oncology | SURF | 4/19/2018 | Biologics | P1 | 306 | P1 | 37 |
| Unum Therapeutics | UMRX | 4/3/2018 | Biologics | P1 | 286 | P1 | 48 |
| Arcus Biosciences | RCUS | 3/14/2018 | Biologics & Targeted small molecules | P1 | 503 | P1 | 369 |
| | | | | Avg | 304 | | |

Publicly Traded Companies with Comparable Technology Platforms

| Company Name | Ticker Symbol | IPO Date | Focus/Technology | Lead Asset Stage at IPO | Pre-Money Mkt Cap (\$M)* | Current Stage of Most Advanced Asset | Current Market Cap (\$M) |
|---------------------|---------------|----------|------------------------------------|-------------------------|--------------------------|--------------------------------------|--------------------------|
| Zymeworks | ZYME | n/a | Biologics - Multiple disease areas | n/a | n/a | P2 | 1,100** |
| Aplynx [†] | n/a | n/a | Biologics - Multiple disease areas | n/a | n/a | Registration [‡] | 4,800* |

*Incl. exercised over-allotment shares; Pre-Money Mkt Cap = (Comm Sh Out Post Offer - Comm Sh Offered) x Price Per Sh

**approximate value as of market close, 10/15/19

†company was acquired by Sanofi in June 2018 for \$4.8B

‡at the time of the acquisition by Sanofi, Aplynx's most advanced product was under review for commercial licensure by the FDA and EMA

Sources: Company websites, Market data, SEC Filings

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: ONS).

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, Chardan, and Senior Analyst and Portfolio Manager at Salaysny 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, Ilex 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.

Company Highlights

Sonnet is a compelling opportunity

A Dynamic Platform For Biopharmaceutical Development

- Sonnet controls an enabling technology for innovating therapeutic products across multiple disease areas
- As a modular, plug-and-play construct capable of being linked to multiple different classes of biologic chemical entities, both for single- and bi-specific mechanisms, we believe F_HAB is unparalleled in its potential

Large Commercial Targets

- We are developing our proprietary pipeline of differentiated therapeutic candidates to address the high unmet needs of robust oncology markets
- Internal opportunities abound in oncology with substantial upside available through external licensings and partnerships

Financial Strength

- Up to \$100 million of capital available from our strategic investor
- Long-term stability

