



# **Acquisition of Enteris BioPharma**



**Collaborative Approach to Life Science Financing** 

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# Agenda

- Acquisition Highlights and Rationale
- Peptelligence® Technology & Business Model Overview
- Internal 505(b)(2) Pipeline
- Enteris Financial Overview





#### **ACQUISITION HIGHLIGHTS AND RATIONALE**

## Synergistic & Value Enhancing

# Highly Favorable Deal Economics

"Game-Changing" Platform Technology

Strong Company;
Positioned for Success

#### **Acquisition Rationale**

- Natural extension to SWK's existing royalty monetization business, which generates income via royalties on life science products in a mix of structures
- Enteris offers opportunity to create wholly-owned portfolio of milestones and royalties on IP-protected biotherapeutics with substantial upside optionality
- Industry comps Ligand Pharmaceuticals and Emisphere Pharmaceuticals highlight significant potential
- Attractive valuation with SWK buying undervalued portfolio of "call options" of current & future licenses, owned drug candidate assets, and manufacturing operations
- Risk-adjusted economics from existing/expected licenses anticipated to exceed purchase price
- SWK believes near to medium term licenses may exceed \$50.0mm of milestones and royalties
- Peptelligence<sup>®</sup> enables injectable-to-oral conversion of peptides and difficult to formulate small molecules
- Targets substantial market and serves as cornerstone for "asset-light" licensing revenue model
- Franchise-like model leverages partners' significant R&D and marketing/commercialization spend
- Existing 505(b)(2) pharmaceutical development candidates plus ability to internally expand owned-product portfolio creates engine for additional future licenses
- Enteris possesses proven technology, clinical experience and in-house manufacturing which is unique compared with peers, some of which sport multi-hundred million dollar market values
- Potential to expand Peptelligence platform via acquisition of dosing technologies and CDMO assets



### **Enteris Corporate Overview**

# Proven Technology, Late-Stage Commercial Partnerships, and Internal Pipeline

#### Drug Delivery Technology

- Peptelligence technology allows for oral delivery of drugs that are typically injected, including peptides and BCS class II, III, and IV small molecules
- Extensive intellectual property estate with protection through 2036

#### Internal 505(b)(2) Pipeline

- Ovarest<sup>®</sup> (oral leuprolide tablet)
  - First indication: Endometriosis
- Tobrate<sup>TM</sup> (oral tobramycin tablet)
  - First indication: Uncomplicated Urinary Tract Infection
- Oral Octreotide Tablet
  - First indication: Neuroendocrine tumors

#### **Commercial Platform**

- Generates revenue three ways:
  - Formulation and development work
  - ✓ Clinical trial tablet manufacturing
  - ✓ Technology licenses consisting of milestones and royalties
- Peptelligence licenses with Cara Therapeutics, Ferring Pharmaceuticals and R-Pharm, and development work with several large pharmaceutical partners

#### **Company Highlights**

- Privately held company based in Boonton, New Jersey
- To operate as a wholly-owned subsidiary, run by current experienced team
- Expected to be profitable including anticipated license-related revenue



#### **Transaction Overview**

- \$21.5mm paid upfront to acquire 100% of Enteris' capital stock
- Proceeds from Cara Therapeutics licensing agreement, which includes milestone payments and low-single digit royalties on sales of Oral Korsuva<sup>TM</sup>:
  - Seller will receive 100% of \$8.0mm upfront payment
  - SWK will receive 60% of the first milestone payment
  - SWK will receive 25% of all other milestone payments until seller receives \$32.75mm in aggregate consideration
  - License revenue split 50%/50% thereafter
  - SWK portion of this license's economics are expected to be greater than the purchase price
- If out-licensed, proceeds for Enteris' 505(b)(2) drug candidates Ovarest and Tobrate
  - SWK to receive 40% until seller receives \$3.0mm on each asset
  - SWK to receive 70% of milestone and royalty proceeds thereafter
- If out-licensed, SWK will receive 90% of Enteris' 505(b)(2) octreotide oral drug candidate proceeds
- Enteris to operate as a stand-alone business unit with the existing management team reporting directly to SWK CEO Winston Black

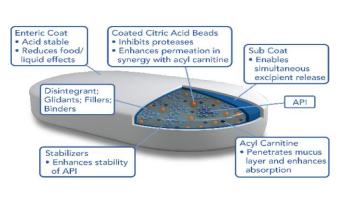


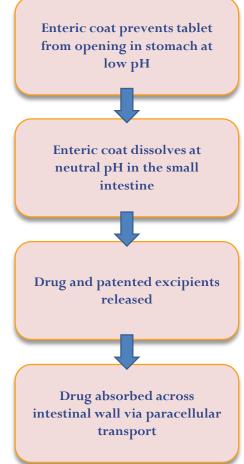


PEPTELLIGENCE® TECHNOLOGY & BUSINESS MODEL OVERVIEW

## Peptelligence Overview

- Formulation technology that enables oral delivery of many peptide and small molecules that have poor permeability across the gut
  - Peptides are generally not bioavailable with oral administration as they are degraded in the digestive tract
- Applicable to New Molecular Entities as well as reformulations of existing molecules
- Combines two key active excipients that solubilize API and enhance crossmembrane transport
- Over 1,500 patients have been dosed with drugs that utilize the technology with no serious side effects related to Peptelligence
- Patent protected through 2036 with 56 issued U.S. and foreign patents, as well as 15 pending U.S. and foreign patent applications
  - Current Enteris team members authored key patents and are actively expanding patent portfolio







## **Licensing Opportunity**

# Injectable-to-Oral Conversion

- Oral delivery is attractive for supporting patient compliance, particularly for indications that require chronic, outpatient therapy (Insulin for example)
- Franchise-like/asset light model: partners license Peptelligence and fund the substantial R&D and marketing dollars for FDA approval and commercialization

#### Peptide Therapeutics

- Top 10 "peptide" focused pharma companies have 145 publicly disclosed peptides in their pipelines
  - Enteris has existing relationships with three of these companies
- Over 60 peptide drugs are approved in the United States and other major markets

#### Small Molecule Therapeutics

- Peptelligence has been shown to improve the oral bioavailability of poorly permeable small molecules
- An additional large market opportunity

# High Upside Growth Potential

- Given the substantial market opportunities, SWK anticipates investing in Enteris' business development function to facilitate greater outbound marketing and customer education to secure additional pharmaceutical development relationships
- Peptelligence may have applicability to additional modalities and SWK anticipates expanding the target market through low-cost, internal development and potential M&A



## **Current Pharma Relationships**

• The Peptelligence technology has been licensed by three pharmaceutical partners:

Peptelligence Signed Licenses				
Company	Molecule	Indication	Stage	
R-Pharm	Tbria oral calcitonin	Post-menopausal osteoarthritis	P 3	
Cara Therapeutics	Oral Korsuva	Pruritus (multiple settings)	P 2	
Ferring Pharmaceuticals	Not disclosed	Injectable therapeutic	Pre-clinical	

Source: Company websites and public filings

- Enteris has material relationships with an additional four pharmaceutical companies covering multiple molecules
- Additionally, Enteris has a deep business development pipeline
  - Enteris targets at least four incremental molecule feasibility studies per year with one signed YTD 2019
  - With additional business development resources, SWK believes the number of annual feasibility studies can double
- SWK believes multiple pharmaceutical development partners could sign formal Peptelligence license agreements over the near to medium term



# Cara Oral Korsuva<sup>™</sup> Program Overview

- Cara Therapeutics has licensed Enteris' Peptelligence technology for use in its Oral Korsuva programs
  - The oral program is based on the same novel "kappa" receptor agonist as Cara's more advanced intravenous formulation
  - In May 2019, announced Phase 3 results of the KALM-1 trial, with intravenous Korsuva<sup>™</sup> achieving statistically significant improvements in pruritus in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus
- As of July 10, 2019, Cara had disclosed oral Korsuva<sup>™</sup> is being developed in three indications:

					Uses Enteris Peptelligence	
Program	Formulation	Stage	Next Data Point	Notes	IP?	
CKD-associated pruritus (aP)	Injection	P 3	KALM-2: Topline data expected in 2H19	KALM-1: Positive topline data reported May 2019	No	
CKD-aP in non-dialysis patients	Oral	P 2	P 2 data expected in 2H19		Yes	
Chronic liver disease aP	Oral	P 2	P 2 trial initiated June 2019		Yes	
Atopic dermatitis	Oral	P 2	P 2 trial initiated July 2019		Yes	

Source: Cara public disclosures

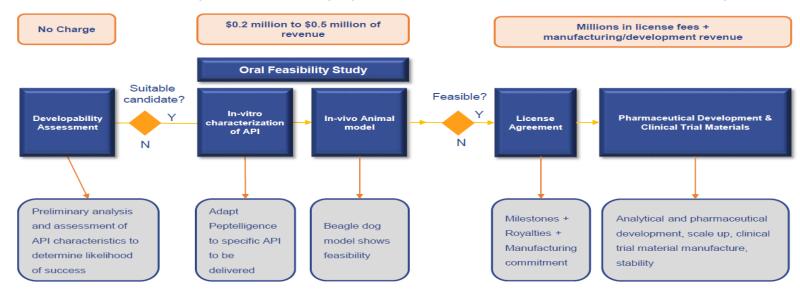
"We are pleased to formalize our ongoing work with Enteris and look forward to the continued advance of our Oral KORSUVA program, which now includes three Phase 2 clinical trials in pruritus settings," stated Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "Effective treatment of pruritus remains a significant unmet need in patients with atopic dermatitis, liver disease and chronic kidney disease, adding to their discomfort and seriously impacting patients' quality of life, including sleep disruption, altered eating habits, anxiety and depression. We believe that KORSUVA may provide a potential, first-in-class therapeutic to treat pruritus across clinical populations, and the ability to deliver it via an oral tablet formulation expands patient accessibility to the benefits of the product, if approved."

Source: August 21, 2019 Enteris press release

• Cara is publicly traded and provides frequent updates on Korsuva; SWK encourages investors to review Cara's website and public investor filings for additional details

### **Technology Platform Economic Model**

- Relationship begins with feasibility and development work where Peptelligence technology is tested on partner's molecule; Enteris is typically
  paid for this work
- Post optimization work, Enteris generally negotiates a license agreement with partner
  - Timing of license execution usually when molecule moves into the clinic, although will vary depending on risk analysis
- Licenses typically include upfront payments, ongoing clinical and sales-based milestones, and royalties on product sales
  - SWK believes near to medium term licenses may exceed \$50.0mm of milestones and royalties
- Importantly, partners fund all R&D; an asset-light model leveraging partners' substantial R&D and future marketing spend





#### Manufacturing Overview

# Expertise and Capabilities

- Enteris has 23 years of manufacturing experience with a history of quality focus and regulatory compliance
- Expert in handling and processing high-potency API
- Current facility exceeds 30,000 square feet and can manufacture clinical trial material through Phase 2
- From 2016 to 2018 manufacturing revenue has averaged \$4.5mm per annum

#### Growth Opportunity

- SWK believes the market for high-potency CDMO services is an attractive niche
- SWK expects to invest a modest amount of capital to build out manufacturing capabilities, which will allow Enteris to manufacture Phase 3 and commercial products
  - Larger facility will support an additional \$25.0mm of annual manufacturing revenue
  - Design accommodates stringent high potency safety requirements

# Maximizing Upgraded Facility

- Once the build out is complete, SWK expects Enteris to pursue deeper manufacturing relationships with developmental clients and to sign new pharmaceutical partners
- Build out should extend partner manufacturing relationships to the commercial-stage
- Expanded manufacturing is important in demonstrating organization's capabilities to potential partners





#### **INTERNAL PIPELINE**

## **Internal Pipeline Summary**

- Enteris has applied the Peptelligence technology to off-patent molecules that are not available in oral formulations to create proprietary, patent-protected reformulation products
- In 2017 and 2018 Enteris incurred \$1.4mm and \$0.5mm of incremental spend on internal product clinical development
  - Excludes salary allocation for full-time employees who spent a minority of time on these projects

Ovarest Oral Leuprolide Tablet for Treatment of Endometriosis	<ul> <li>Phase 2a completed; Clear signal to progress to Phase 2b</li> <li>Market opportunity: 6+ million U.S. women and \$200+ million in annual U.S. sales</li> <li>Likely significant value in follow-on indications</li> </ul>
Tobrate Oral Tobramycin Tablet for Treatment of uUTI	<ul> <li>Phase 1a completed</li> <li>QIDP and Fast Track Status granted by FDA</li> <li>Market opportunity: 10 million U.S. women and \$400+ million in annual U.S. sales</li> </ul>
Octreotide Oral Tablet for Treatment of Neuroendocrine tumors	<ul> <li>Pre-clinical work underway</li> <li>\$2 billion market in acromegaly and other indications</li> </ul>
Others	• Enteris has identified additional existing injectable molecules that are potential fits for Peptelligence and that demonstrate attractive commercial characteristics

## Internal Pipeline Strategy

- SWK may selectively fund the internal pipeline to achieve milestones to optimize out-licensing economics
  - SWK views the internal pipeline as an extension of the licensing business model and does not currently anticipate becoming a commercial pharmaceutical organization
  - In the near-term, any internal pipeline funding expected to be modest and inline with historical levels
  - SWK does not currently intend to fund large clinical studies
- In the intermediate-term, SWK may evaluate establishing a separate subsidiary(ies) to seek dedicated, off-balance sheet funding
  - Potential for Enteris to "drop" additional 505(b)(2) assets into the subsidiaries as additional product candidates are identified
  - SWK views lending partner Harrow Health as a pioneer in this structure
- Post out-licensing, Enteris will retain economics through future milestones and royalties, as well as, revenue through ongoing manufacturing relationships
- SWK expects economic terms from out-licensing the internal pipeline will be superior to its traditional IP licensing business given the 'owned-asset' nature of the pipeline





#### **FINANCIALS**

#### **Enteris Historical Financials**

- Revenue averaged \$5.9 million from 2016 to 2018
- Revenue can be lumpy based on timing of clinical trial material manufacturing sales and license payments
- SWK expects Enteris will be profitable inclusive of anticipated license payments

Enteris Summary GAAP Financials					
(\$ in mm)	2016	2017	2010	11110	11110*
	 2016	2017	2018	 1H18	1H19*
Revenue	\$ 7.1	\$ 7.0	\$ 3.7	\$ 2.1	\$ 4.6
EBITDA**	\$ (4.4)	\$ (0.5)	\$ (2.6)	\$ (1.5)	\$ 0.7
Reconciliation to EBITDA**:					
Net loss	\$ (2.6)	\$ (3.0)	\$ (5.0)	\$ (2.8)	\$ (1.0)
Subtract: income tax benefit	\$ (3.6)	\$ -	\$ -	\$ -	\$ -
Subtract: net interest and other (income)	\$ (0.6)	\$ 0.1	\$ 0.0	\$ -	\$ 0.1
Add: transaction (expense)	\$ -	\$ -	\$ _	\$ -	\$ 0.4
Add: depreciation & amortization	\$ 2.4	\$ 2.4	\$ 2.4	\$ 1.2	\$ 1.2
EBITDA**	\$ (4.4)	\$ (0.5)	\$ (2.6)	\$ (1.5)	\$ 0.7



<sup>\* 1</sup>H19 results preliminary and subject to change; 1H19 results include transaction costs of approximately \$0.4mm.

<sup>\*\*</sup> EBITDA is a non-GAAP financial measure management believes provides useful information to investores regarding the financial condition and results of operations. The table eliminates income tax benefit, net interest expense, non-recurring transaction expenses, and non-cash expenses (depreciation and amortization).

## Synergistic & Value Enhancing

Enteris now has access to capital and resources that it can direct towards expansion and growth opportunities

Enteris and SWK are aligned in the long-term vision for Peptelligence and business strategies to maximize its value

Additional revenue opportunities achievable through expansion of Enteris' manufacturing capabilities and re-modeling of Enteris' assets

Enteris and Peptelligence provide foundation to build an ecosystem of externally and internally derived license agreements and a whollyowned milestone and royalty portfolio





#### Cara Therapeutics Enters into Commercial License Agreement with Enteris BioPharma, Inc. for Peptelligence® Oral Formulation Technology

August 21, 2019

#### Peptelligence® technology currently used in Oral KORSUVA™ formulation

STAMFORD, Conn., Aug. 21, 2019 (GLOBE NEWSWIRE) — Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on the treatment of pruritus by selectively targeting peripheral kappa opioid receptors, today announced that it has entered into a non-exclusive commercial license agreement with Enteris BioPharma, Inc. for oral formulation rights to Enteris' Peptelligence <sup>®</sup> Technology.

"We are pleased to take another important step in advancing Oral KORSUVA" as a potential novel treatment for chronic pruritus by entering into this commercial formulation license," said Derek Chaimers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "With three ongoing Phase 2 trials across a range of patient populations for whom pruritus remains a significant unmet need, we are now well positioned to continue Oral KORSUVAs development and potential future commercialization."

#### Summary of the License Agreement

Under the terms of the License Agreement, Enteris granted Cara a non-exclusive license to its Peptelligence Technology to develop and commercialize Oral KORSUVA in any indication worldwide, excluding South Korea and Japan. Enteris will receive an upfront payment of \$8 million, including \$4 million in cash and \$4 million in Cara common stock. Enteris is also eligible to receive development, regulatory and tiered commercial milestone payments, as well as low, single-digit royalties based on net sales in the licensed territory. Cara retains the right to buy out the royalty obligation for a period of two years under prespecified conditions.

#### **About Cara Therapeutics**

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alloviate pruritus by selectively targeting peripheral kappa opicid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA (CR845/difelikefalin), a first-in-class KOR agonist that targets KORs located in the peripheral nervous system, and on immune cells. In a Phase 3 and two Phase 2 trials, KORSUVA (CR845/difelikefalin) Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in pruritus-related quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP), and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is in Phase 2 trials for the treatment of pruritus in patients with chronic kidney disease, atopic dermatitis, and primary biliary cholangitis.

The FDA has conditionally accepted KORSUVA<sup>TM</sup> as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

#### Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the potential for Oral KORSUVA to be a therapeutic option for pruritus and the advantages of entering into the license agreement with case such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Cara's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended December 31, 2018 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

