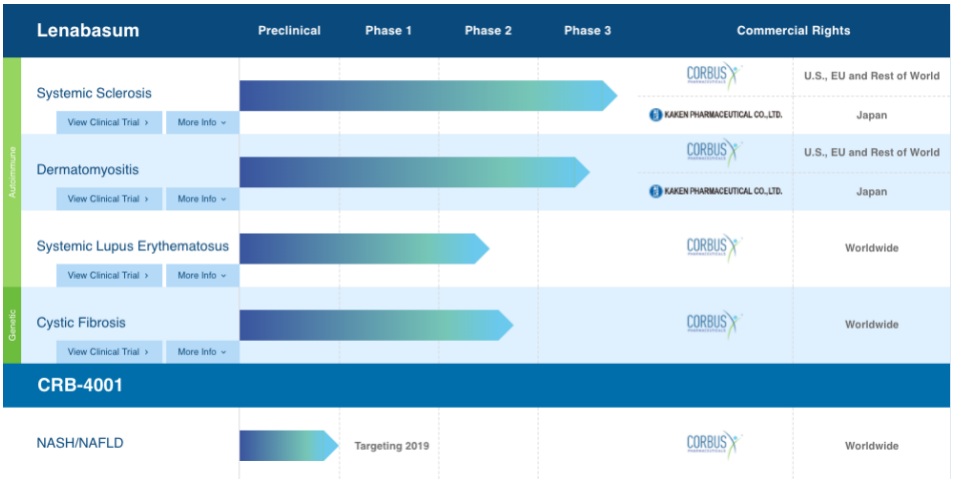
Corbus Pharmaceuticals - CRBP (7/5/19)

Description: Corbus Pharmaceuticals is a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases by leveraging its pipeline of endocannabinoid system targeting synthetic drug candidates. The company is based out of Norwood, MA and was founded in 2014 out of a reverse merger from JB Therapeutics.

Ticker: CRBP
Price: $6.84
Market Cap: $445M
Performance: +18.0% YTD

Analysis

Unlike many smaller pharma companies today that have a deep and young pipeline, Corbus Pharma is the opposite. Currently, CRBP is extremely dependent on the success of two products: Lenabasum and CRB-4001.



Lenabasum is awaiting a potential Phase 3 approval. It is a rationally-designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2). CB2 is expressed on activated immune cells, fibroblasts, muscle cells, and endothelial cells.

What are these endocannabinoid and C2 receptors being spoken of?

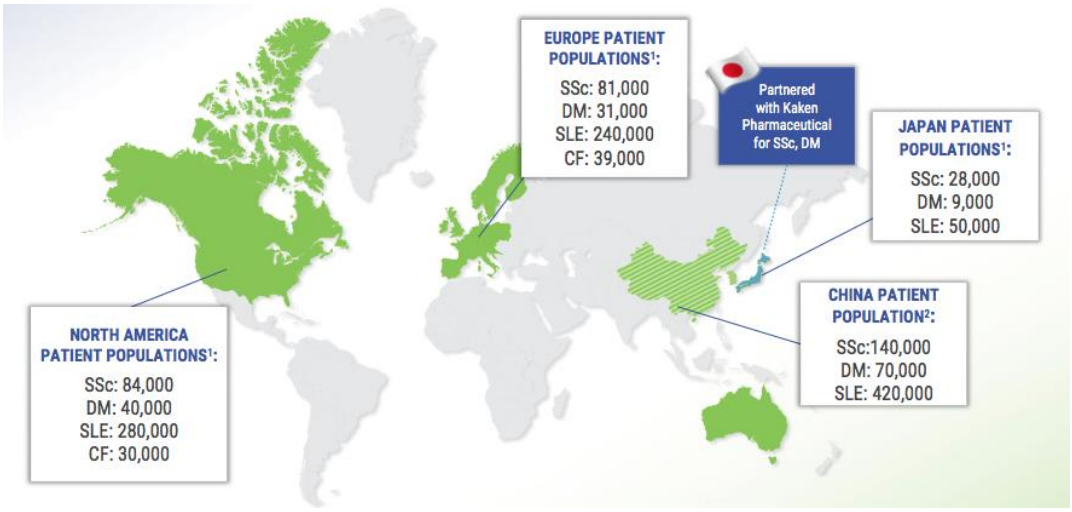
The endocannabinoid systems (ECS) is active when your body is outside of its normal environment and needs to make adjustments. For example, your body activates the ECS to help correct it when you're really hot so you begin to sweat.

The ECS does this via cannabinoid receptors found in select tissues. We have (at least) two types of cannabinoid receptors:

- CB1 which is in the central nervous system (brain and nerves of the spinal cord)
- CB2 which is in the peripheral nervous system (nerves in your extremities), the digestive system, and specialized cells in the immune system. This is what CRBP is referring to.

In other words, Lenabasum is a synthetic compound that targets a network of neurotransmitters in the human (ECS) to temper inflammation and fibrosis. Last year the stock had a huge jump based on this news and the CEO, Yuval Cohen was even invited on CNBC. Cohen said, “None of our drugs is similar to the plant-derived cannabinoids — they’re known as phytocannabinoids. Our drugs are manmade. They’re rationally designed,” he told Cramer on ‘Mad Money.’ “So the one thing they’re not, for example, is they’re not psychoactive. They don’t change your mood or the way you feel.”

In both animal and human studies conducted to date, Lenabasum has induced the production of Specialized Pro-resolving lipid Mediators (“SPMs”) that activate pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum is also believed to have a direct effect on fibroblasts to limit production of fibrogenic growth factors and extracellular connective tissue that lead to tissue fibrosis (scarring). Data from animal models and human clinical studies suggest that Lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). It is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.



Lenabasum is being created to cure the following illnesses:

Systemic Sclerosis (SSc) – *Currently in Phase 3*

- It's is a chronic, rare systemic autoimmune disease characterized by inflammation and fibrosis
- Affects ~200,000 people in the U.S., EU and Japan
- Has the highest mortality rate among the systemic autoimmune diseases
- There aren't any drugs currently approved by the U.S. FDA for treatment of SSc

Dermatomyositis (DM) – *Currently in Phase 3*

- DM is a rare and serious autoimmune condition characterized by skin and muscle inflammation
- Affects ~80,000 people in the U.S., EU and Japan
- 5-year mortality as high as 30%

Cystic Fibrosis (CF) – *Currently in Phase 2b*

- CF is a life-threatening genetic disease characterized in part by chronic lung inflammation that leads to lung damage and fibrosis
- CF affects ~70,000 people in U.S. and EU

Systemic Lupus Erythematosus (SLE) – *Currently in Phase 2*

- Systemic lupus erythematosus is a severe and sometimes life-threatening systemic autoimmune disease
- Affects approximately 550,000 people in the U.S., EU and Japan

CRBP hopes to get approval for SSc by summer of 2020 & commercialize the product in 2021.

Company	Drug Candidate	Phase	Indication	Type of Compound
CORBUS PHARMACEUTICALS	Lenabasum (CB2 agonist)	Phase 3 in SSc & DM Phase 2 in CF & SLE	Inflammation/Fibrosis (Immune system)	Small molecule (NCE)
	CRB-4001 (CB1 inverse agonist)	Preparing for Phase 1	Inflammation/Fibrosis (Liver)	Small molecule (NCE)
janssen	Nimacimab (CB1 antagonist)	Phase 1 completed	Liver	mAb
janssen	JNJ-42165279 (FAAH inhib)	Phase 2 in Autism Spectrum Disorder & Social Anxiety Disorders	CNS	Small molecule (NCE)
ABIDE	ABX-1431 (MGLL inhib)	Phase 2 in Tourette Syndrome, Acquired by H. Lundbeck A/S	CNS	Small molecule (NCE)
VALEANT	Cesamet (nabilone) (THC)	Commercial	CNS	Small molecule (NCE)
abbvie	Marinol® (THC)	Commercial	CNS	Phytocannabinoid
GW pharmaceuticals	Epidiolex® (CBD)	Commercial	CNS	Phytocannabinoid
GW pharmaceuticals	Sativex® (CBD & THC)	Commercial in EU	CNS	Phytocannabinoid

In comparison to competition, CRBP has a pretty strong head start. Furthermore, what differentiates Lenabasum from its nearest Phase 3 competitors is that it is said to halt disease progression by correcting the underlying deficiency that may be contributing to the pathophysiology of DM. Lenabasum is being developed as a therapy for overall DM disease activity and if endorsed by the FDA, Lenabasum should have an addressable market of 80,000 patients in Europe/US/Japan with high pricing power all to itself in the first few years following approval.

CRBP's other product, CRB-4001 is Corbus' NAFLD/NASH drug. The product is in very early stages targeting Phase 1 approval sometime this year and is not in a front-running position like Lenabasum as there are many other NASH players much further along and closer to FDA approval.

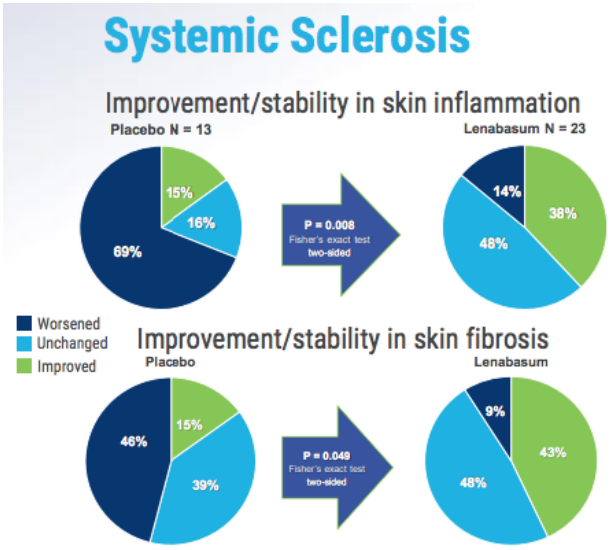
What is NASH or NAFLD? NASH (nonalcoholic steatohepatitis) is an obesity-related complication, that is believed to affect about 30M Americans. Its precursor, nonalcoholic fatty liver disease (NAFLD), affects ~89M Americans, including people in their 20s and 30s and is said to be a $35B addressable market.

The estimated global prevalence of NAFLD and NASH has risen rapidly in parallel with the dramatic rise in population levels of obesity and diabetes. NAFLD now represents the most common cause of liver disease in the Western world. In the United States alone, the prevalence of NASH was estimated to total 16.5 million cases and is projected to reach 27 million cases by 2030, with similar trends occurring globally. By 2020, NASH is expected to surpass hepatitis C as the leading cause for liver transplantation, and liver-related deaths in the NAFLD population are expected to increase by more than 150% in the next 15 years. The annual economic burden associated with NAFLD and NASH in the United States was estimated to have been over $100 billion in 2016.

Of the estimated 64 million patients in the United States with NAFLD, approximately 10%–20% will progress to NASH over time. Of these NASH patients, approximately 10%–15% will progress to cirrhosis by advancing one fibrosis stage every seven years. The mortality rate of NASH patients with fibrosis has been estimated at 1.5%–3.5% per year, largely due to cardiovascular disease, followed by liver-related causes.

What we can say is that while CRBP's pipeline isn't deep, it is targeting very large problems. The risk most certainly lies in Lenabasum, though. For example, if Lenbasum doesn't get the FDA approval many investors are waiting for then it's going to be years before any revenues or profits will be coming CRBP's way. Currently, the company anticipates a commercial rollout by 2021 but that doesn't mean it's a guarantee by any measure.

Below is a chart, displaying how patients felt after using Lenabasum vs. the placebo in SSc:



The studies show that in skin inflammation, 38% said their conditions improved vs. the placebo which was 15%. With skin fibrosis, 43% said their conditions improved vs. the placebo at 15%.

Here's something pretty interesting and is quite a head scratcher, though. If Lenabasum is targeting such a crucial and life threating illness and is arguably one of the few with a product that could potentially be a cure, why did the FDA not give Lenabasum the thumbs up for a breakthrough therapy designation?

For those unaware, a company can apply to the FDA to obtain breakthrough therapy designation if it believes its drug:

1. Addresses a serious or life-threatening condition
2. Demonstrates preliminary clinical evidence that it may have substantial improvement on at least one clinically significant endpoint over available therapy.

What concerns CUBE is that the FDA must have not been fully convinced with the results from Lenabasum's Phase 2 data over the placebo otherwise why would they deny the request from Corbus when it appears to satisfy both requirements?

At the same time, CRBP was given the 'OK' by the FDA for fast track status. I just figured that based on the studies they would have received both.

Fundamental Review

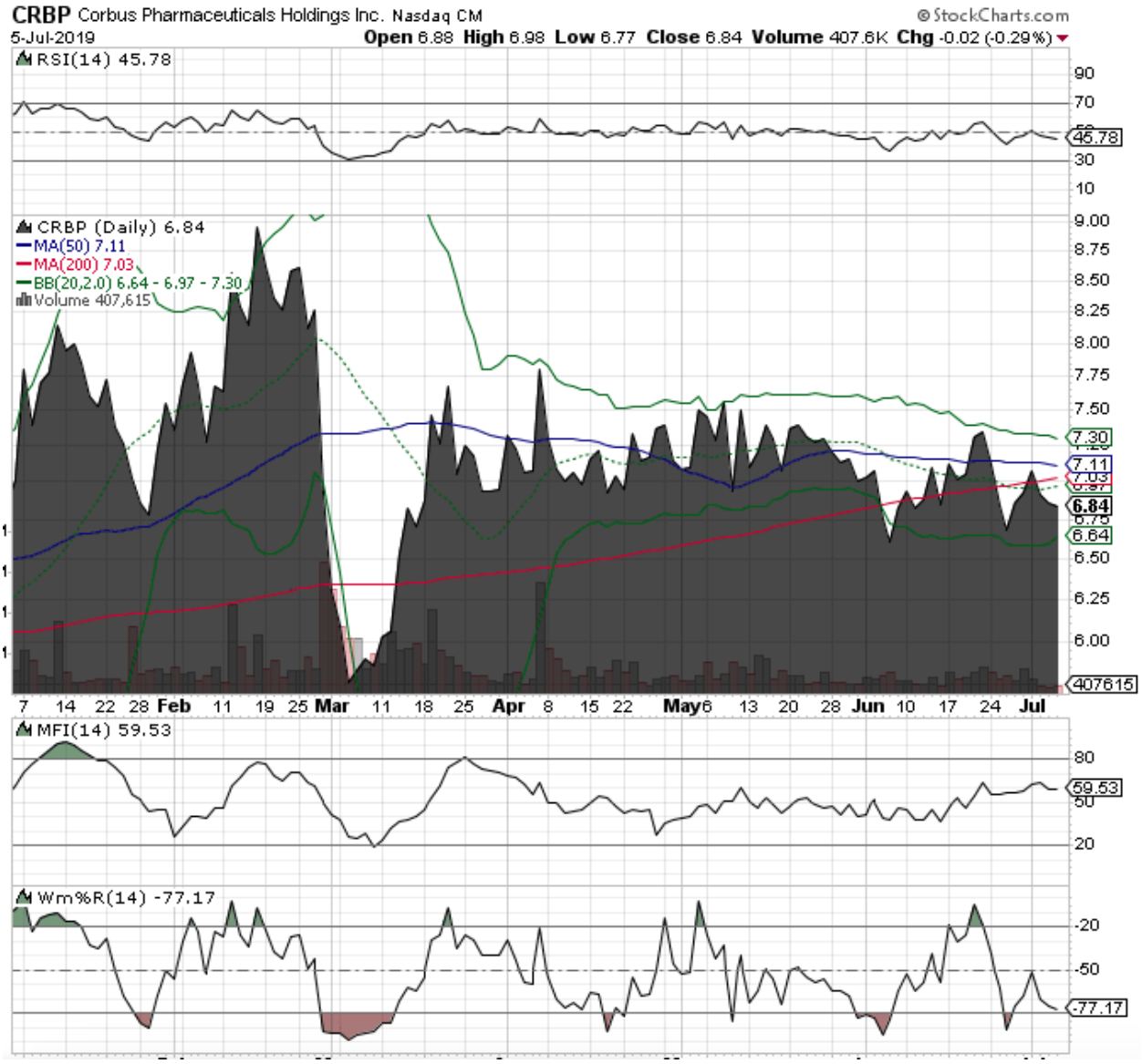
Fundamentally, the picture is never pretty with pharma companies in this stage as they are all either financed with equity or debt and never free cash flow from operations.

Corbus just raised an additional $40M in January through the issuance of approximately 6.2M shares at $6.50. The company now sits on about $90M in cash at the end of Q1 2019 – the highest amount we've seen from the company. This amount of cash should easily get them through the rest of the year and a good portion of 2020 unless they plan on ramping up R&D or making any acquisitions. The company has about $7M in long-term debt and a current ratio of 1.8x and quick ratio of 1.7x meaning that liquidity and solvency isn't really a big risk at this point in time.

Out of the 64M shares outstanding, 58M are available for trading and of that 58M, 16.3M are shorted. This puts the amount of shares short as a percentage of the float (16.3/58) at around 28%. The reason for mentioning this is to show that any indication of good news can send shares higher as on average the stock trades 900K shares a day. That implies that if everyone single shorter wanted to cover, it would take approximately 18 trading days to cover their position without exploding the stock higher. This doesn't mean it's going to happen but just gives investors an idea of what can potentially happen. The flipside is that every little pop could be shorted down and that those who are short could have every reason to be.

As for insiders, there has been little buying or selling over the last year. The most recent transaction was a purchase of about 1,400 shares at $7.20 by Barbara White, the Chief Medical Officer.

Technical Review



When looking at the charts, shares are neither oversold nor overbought but lean closer to oversold. CRBP has been unable to hold its 50DMA or 200DMA of $7.11 and $7.03, respectively which is not a good sign as those two levels will now act as areas of resistance to the upside. If the trend continues downward, CRBP has to hold $6.64 and then $6.39. If it is unable to hold $6.39 it could revisit lows made back in March of $5.84.

For CUBE, this investment simply doesn't fit our profile. While CRBP is getting close with Lenabasum, it is still a one trick pony for the foreseeable future and if Lenabasum doesn't get the FDA approval that Corbus needs it could be years upon years before anything else

materializes. At that point, CRBP would pretty much be a Phase 1 NASH play for the foreseeable future which isn't anything too special as there are many competitors that are much further along in that space. In summation, this is a play on Lenabasum's success given how narrow Corbus' pipeline is. It's a speculative and risky investment and this must be taken into consideration when deciding whether or not you want to make Corbus part of your portfolio or not.

CUBE personally prefers companies with deeper pipelines this way the company is less dependent if one drug doesn't get the green light from the FDA.