Elle Investments Research Report: SPPI

Company: Spectrum Pharmaceuticals, Inc.
Symbol: **SPPI**
Analysis Date: 8/9/19 – UPDATE: 1/7/20
Analysis Price: $3.22
Price Target (PT): $8.15
Upside: **153%**
Dividend: NA
Recommendation: **Buy**

SPPI: 1-Year Chart

Source: Seeking Alpha

INVESTMENT THESIS:

The December 2019 phase 2 data readout for exon-20-mutant NSCLC showed that poziotinib will likely not be the miracle drug that the market had been hoping for. Nevertheless, it should still capture some market share. After taking a renewed look at Rolontis, we conclude that the punishment has been excessive. This is no longer a top pick, but the great cash position make SPPI a Buy.

LIQUIDITY POSITION: Excellent

As of 3Q19, SPPI had cash and cash equivalents of $252M, with a quarterly cash burn of about $30M. This is more than enough to fund their trials and cover any regulatory milestone payments for ROLONTIS or poziotinib that might be triggered in the near future. Their cash balance also provides enough to expand the salesforce when the time comes (keep in mind that current SG&A spending already includes “a core group of commercial talent” that was retained after the divestiture to Acrotech for the specific purpose of launching poziotinib and ROLONTIS). We think the risk of dilution is low.

COMMERCIAL PROSPECTS: Good

Poziotinib

Poziotinib is an orally administered TKI which has been developed to target tumors with EGFR and HER2 with exon 20 insertion mutations. The data readouts that caused investors to be very bullish in late 2017 were for NSCLC trials, but the hope is that it can eventually be used to treat other non-lung exon 20 mutant tumors.

SPPI licensed poziotinib from Hanmi Pharmaceuticals on March 4, 2015. They own worldwide rights (except for Korea and China) and are required to pay Hanmi regulatory milestones of up to $33M, commercial milestones of up to $325M, and a royalty of low- to mid-teen digits on net sales.

Over the past decade, lung cancer treatment has evolved from a “one-size-fits-all” philosophy to a more precise and targeted approach based on underlying genetic and molecular make-ups. Among the earliest mutations identified are the exon-19 deletions, exon-20 insertions, and L858R mutations (found on exon-21).

For those that are particularly interested, the article in Nature magazine titled “Targeting EGFR exon-20 insertion mutations in non-small cell lung cancer” (published on March 8, 2019) goes heavy into the science (specifically steric hindrance) behind why therapies targeting exon-20 mutations are proving to be more effective than previous treatments. But to understand the value proposition for poziotinib, it suffices to know the following: 1) the response rates for previous non-exon-20 targeting TKIs have been very poor, 2) the structure of poziotinib has been designed to overcome the hindered binding pocket issues believed to be responsible for the poor response rates of previous TKIs, and 3) poziotinib’s early results represent a dramatic improvement in response rates.

While targeted oncology treatments severely limit the size of the patient pool, the growing body of evidence seems to indicate that it dramatically increases the chance of success for patients that exhibit certain genetic biomarkers.

Response rates for first, second, and third generation TKIs continue to be extremely poor, coming in under 10%. Results for chemotherapy, immunotherapy/immuno-oncology ("IO"), and combo treatments have fared a bit better, but the 20% range is still low. Additionally, the toxicities associated with both IO and chemotherapy need to be considered, and lend support to the notion that a targeted TKI treatment should be the standard of care.

It would have been very remarkable if response rates for poziotinib had stayed above 60% throughout the phase 2 trial at MD Anderson. Unfortunately, successive data readouts (responsible for the decline in the stock price) have seen the ORR come down (most recently) to the 15% range, which does not represent a significant improvement compared with current therapies (keep in mind that the initial goal was to get response rates between 20-30%).

On the safety front, the rates of AEs seen with poziotinib that lead to a dose reduction or discontinuation appear to be right in line with other already approved and marketed TKIs (i.e. afatinib, dacomitinib). The safety profile is not a major concern at this point.

There are still six other Cohorts in the phase 2 ZENITH20 trial that need to report top-line data, so there is a chance that the Cohort 1 ORR of 15% will be an outlier. However, based on the information we have right now, we have reduced our market share estimates significantly. Poziotinib might still make it to market first, but its positioning in the exon 20 mutant NSCLC field is no longer very compelling.

ROLONTIS (eflapegrastim)

The second lead candidate in the pipeline is ROLONTIS, formerly SPI-2012, which has been developed to treat CIN. SPPI licensed ROLONTIS from Hanmi Pharmaceuticals on January 31, 2012. SPPI owns worldwide rights (except for Korea, China, and Japan), and in April 2016 paid about $2M in stock to Hanmi when the first patient in a trial was dosed with ROLONTIS. Going forward, SPPI is required to pay up to $13M in regulatory milestones, up to $225M in commercial milestones, and a royalty of low double-digits to mid-teens on net sales.

Chemotherapy is often very damaging to bone marrow, the site of white blood cell production. A specific type of white blood cells, called neutrophils, are especially important for warding off certain types of bacteria-caused infections. When the body is exhibiting a low neutrophil count (confirmed by blood test), the condition is known as neutropenia. While it can have other causes, neutropenia is often a harmful side effect of chemotherapy.

In 2015 expectations were high immediately following positive phase 2 results which showed that ROLONTIS had achieved non-inferiority against Amgen's (AMGN) multi-blockbuster Neulasta (pegfilgrastim). FBR & Co (which has since been acquired by B. Riley Financial) predicted blockbuster potential (implying annual peak sales of over $1B), given Neulasta's sales of $4.6B in 2014. Since that time, however, commercial expectations have come down significantly. The primary reason for this is the entrance in 2018 of several Neulasta biosimilars, which were priced aggressively at a 33% discount to Neulasta in the hopes of capturing market share.

Early results had suggested that there could have been some differentiation in terms of efficacy between ROLONTIS and Neulasta. But the limited evidence demonstrating ROLONTIS superiority has not been consistent enough, and the emphasis of SPPI's phase 3 trials has been to simply show non-inferiority. ROLONTIS has clearly proven this, across several trials, with respect to both efficacy and tolerability. But at this point, ROLONTIS will eventually enter a crowded market having only shown non-inferiority with Neulasta. Still, we expect ROLONTIS to capture some amount of market share.

FIT Platform (Focused Interferon Therapeutics)

This candidate is in preclinical and phase 1 testing. We have not assigned it any value.

CONCLUSION:

We think that SPPI's stock has been overly punished from the successive data readouts showing the ORR for poziotinib coming down from over 60% to the 15% range. While it's true that poziotinib no longer appears to be a significant step forward in the treatment of exon 20 mutant NSCLC, it should still capture some market share. Along with the other lead candidate ROLONTIS and an excellent cash position, we think SPPI is a Strong Buy.

GLOSSARY:

AE: adverse event
BLA: Biologics License Application
CIN: chemotherapy-induced neutropenia
EGFR: epidermal growth factor receptor
HER2: human epidermal growth factor receptor 2
IO: immunotherapy (immuno-oncology)
NSCLC: non-small cell lunch cancer
ORR: overall response rate (objective response rate)
TKI: tyrosine kinase inhibitor

Note: Additional commentary from Elle Investments can be found at http://elle-investments.com. We welcome your feedback. Additionally, we are thinking of launching a subscription service that would offer early access to our research, along with some other features that investors might find useful (i.e. general portfolio management strategies, live blog updates highlighting our reaction to breaking news, etc.). If you would be interested in subscribing to such a service, please let us know.

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