NGM Biopharmaceuticals - NGM (7/2/19)

Description: NGM Biopharmaceuticals Inc. was incorporated in 2007 and is headquartered in San Francisco, California. They are a clinical-stage biopharmaceutical company that engages in the discovery and development of therapeutics for the treatment of cardio-metabolic, liver, oncologic, and ophthalmic diseases.

Ticker: NGM
Price: $14.47
Market Cap: $953M
Performance: -1.56% YTD

Analysis

NGM operates in a few different spaces but most prominently in the NASH (non-alcoholic steatohepatitis) space. The company IPO'd in April of this year and shares have been pretty flat over the last several months as seen below.

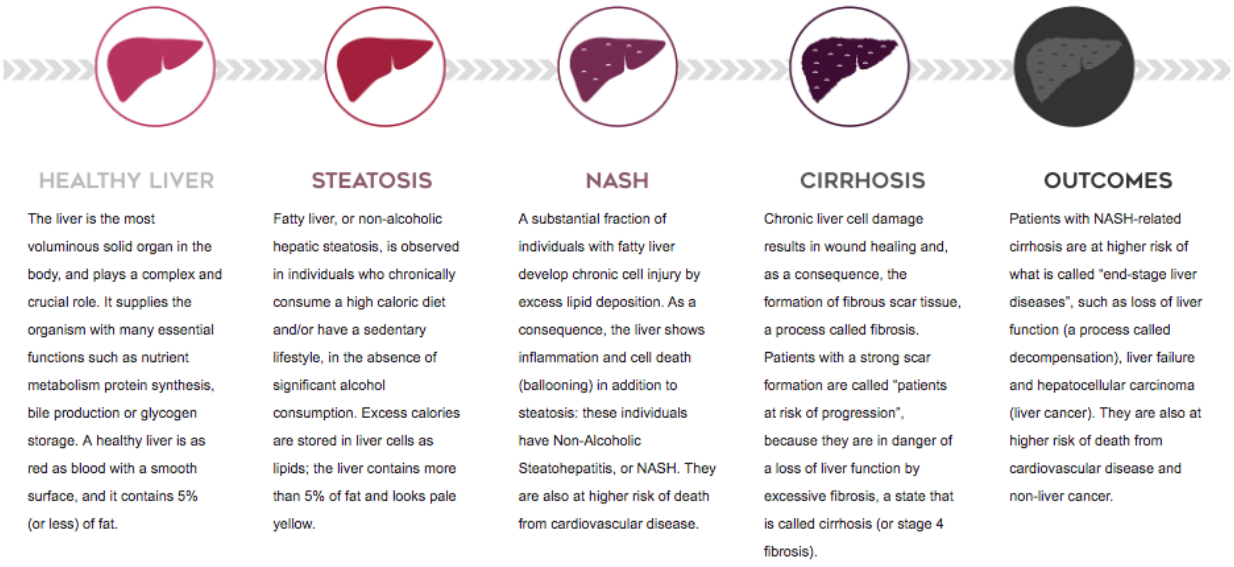
Below is a list of the drugs that NGM is currently working on:

1. NGM282 - an engineered variant of the FGF19 human hormone in Phase 2 clinical trials for the treatment of non-alcoholic steatohepatitis (NASH)
2. NGM313 - an agonistic antibody that selectively activates fibroblast growth factor receptor 1c-beta-klotho, which is in Phase 1b early proof-of-concept clinical trials for use in the treatment of type 2 diabetes and NASH
3. NGM386 & NGM395 – both of which are engineered variants of the GDF15 human hormone for use in the treatment of obesity
4. NGM120, an antagonistic antibody binding glial cell-derived neurotrophic factor receptor alpha-like that is in Phase 1 clinical trials to inhibit the effects of elevated GDF15 levels on cancer anorexia/cachexia syndrome
5. NGM217- an antibody in Phase 1 clinical trials to restore pancreatic islet function and increase insulin production in patients with diabetes
6. NGM621 - an antibody in preclinical studies to decrease levels of a protein implicated in the dry form of age-related macular degeneration

PRODUCT CANDIDATE	PRODUCT DESCRIPTION (DOSING FREQUENCY)	POTENTIAL INDICATIONS	STAGE OF DEVELOPMENT	WORLDWIDE COMMERCIAL RIGHTS
NGM282	FGF19 Analog (Once Daily)	NASH	Phase 2b	NGMBio Wholly-Owned
NGM313 (MK-3655)	FGFR1c/KLB Agonistic Antibody (Once Monthly)	NASH, Type 2 Diabetes	Phase 1b	MERCK Licensed / NGMBio
NGM120	GFRAL Antagonistic Antibody (Long Acting)	Cancer Anorexia/Cachexia Syndrome (CACS)	Phase 1	NGMBio / MERCK Option
NGM217	Undisclosed (Long Acting)	Diabetes	Phase 1	NGMBio / MERCK Option
NGM621	Undisclosed (Long Acting)	Dry Age-Related Macular Degeneration (AMD)	Preclinical	NGMBio / MERCK Option
NGM386	GDF15 Analog (Once Daily)	Metabolic	Phase 1	NGMBio Wholly-Owned[1]
NGM395	GDF15 Analog (Long Acting)	Metabolic	Preclinical	NGMBio Wholly-Owned[1]

As we can see, most of NGM's pipeline still has a long way to go but the leading product right now is definitely NGM282 which operates in the NASH field. Let's discuss this space in a bit more detail.

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 supplant 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.

At this moment in time, the FDA has provided preliminary recommendations to the industry regarding acceptable development pathways for investigational NASH agents as follows:

- Must be tested in NASH patients typically characterized as having a NAS of four or greater and at least one point in each component, with F2, F3 or F4 fibrosis

Fibrosis Score

Fibrosis Stage	Description
F0	Absence of fibrosis
F1	Perisinusoidal or periportal
F2	Perisinusoidal and periportal
F3	Bridging fibrosis
F4	Cirrhosis

(refer to picture on previous page for details)

In Phase 2 clinical trials in NASH, patients taking NGM282 have experienced reductions in liver fat, liver transaminases, hepatocellular ballooning and fibrosis. These results suggest that NGM282 has the potential to resolve disease and reverse fibrosis in NASH patients with moderate to advanced fibrosis. The company plans to initiate a Phase 2b clinical trial of NGM282 in NASH patients with fibrosis stage F2 and F3 in Q2 2019, which will inform dose selection for a Phase 3 clinical trial to support a filing for initial marketing approval. As part of their life cycle management strategy, they also intend to develop a version of NGM282 with an extended half-life, or exposure duration in the blood, which will enable less frequent dosing vs. the current daily dosing right now.

Something we found in their test results do make us a little nervous. There were no serious adverse events reported, though nine subjects withdrew due to adverse events. The most frequently observed adverse events were GI side effects, which were primarily loose stools/diarrhea, nausea and injection site reactions. One subject developed antibodies against NGM282 that appear to cross-react with FGF19. The subject did not demonstrate any biochemical or clinical safety concerns while in the study, though.

While the NASH addressable market is huge, so is the competition.

In 2019, the first class of NASH therapeutics, is expected from:

- Intercept (ocaliva)
- Allergan (cenicriviroc)
- Gilead (selonsertib)
- Genfit (elafibranor)

Phase 3 NASH drug candidates from:

- Madrigal (Phase 3 initiation)
- Galmed

- Galectin

Several Phase 2b NASH data readouts from:

- Inventiva (lanifibranor)
- CymaBay (NASDAQ:CBAY) (seladelpar)
- NGM Bio (NGM282)
- Conatus (NASDAQ:CNAT) (emricasan)
- Enanta (NASDAQ:ENTA) (EDP-305)
- Novartis (NYSE:NVS) (tropifexor)
- Bristol-Myers Squib (NYSE:BMY) (BMS-986036)

Notables:

- Can-Fite (NYSEMKT:CANF) (namodenoson)
- Pfizer (NYSE:PFE) (PF-05221304)
- Viking (NASDAQ:VKTX) will initiate Phase 2b NASH trial for VK2809

Moving along, analyzing management is always a wise thing to do and we want to highlight one individual in particular. NGM's former CEO and Lead Independent Director, David V. Goeddel has already been a part of two companies that have been sold to Merck JUST THIS YEAR.

Here are the two:

On May 21st, 2019, Merck reached a deal to acquire Peloton Therapeutics, and its Phase 3-ready kidney cancer drug, for $1.05B. Goeddel has been the Chairman of Peloton since 2011.

Funny enough, the acquisition came one day before Dallas-based Peloton was expected to go public. Under IPO terms the company set, Peloton could have raised as much as $183 million to fund Phase 3 tests of its lead cancer drug and advance its other programs.

A few months earlier in February of this year, Merck also acquired Immune Design for $300M in cash. On the surface it looks like there wasn't a connection with Goeddel but after doing some digging there is.

11.	Aggregate Amount Beneficially Owned by Each Reporting Person: 3,161,942(1)
12.	Check if the Aggregate Amount in Row (11) Excludes Certain Shares (See Instructions): ☐
13.	Percent of Class Represented by Amount in Row (11): 6.6%(2)
14.	Type of Reporting Person (See Instructions): PN

(1) The Column Group, LP ("TCG LP") has sole voting and dispositive control over 3,161,942 shares of common stock, par value $0.001 per share ("Common Stock"), of Immune Design Corp. (the "Issuer"), except that The Column Group GP, LP ("TCG GP"), the general partner of TCG LP, and Peter Svennilson ("Svennilson") and David V. Goeddel ("Goeddel"), the managing partners of TCG GP, may be deemed to share dispositive and voting power over such stock.

(2) The percentage set forth in row (13) is based on 48,164,828 outstanding shares of Common Stock as of November 5, 2018, as disclosed in the Issuer's Quarterly Report on Form 10-Q filed with the SEC on November 6, 2018.

We know Goeddel is the Managing Partner of The Column Group LLC since 2007 and also serves as a member of the Scientific Advisory Board for the company. According to SEC Filings released a few months before the acquisition, The Column Group owned a 6.6%, or 3.16M shares, stake in Immune Design.

Why does this carry significance? Well, as we just illustrated, Merck is heavily involved in NGM's business and this could be a third setup for an acquisition between Merck and another one of Goeddel's companies.

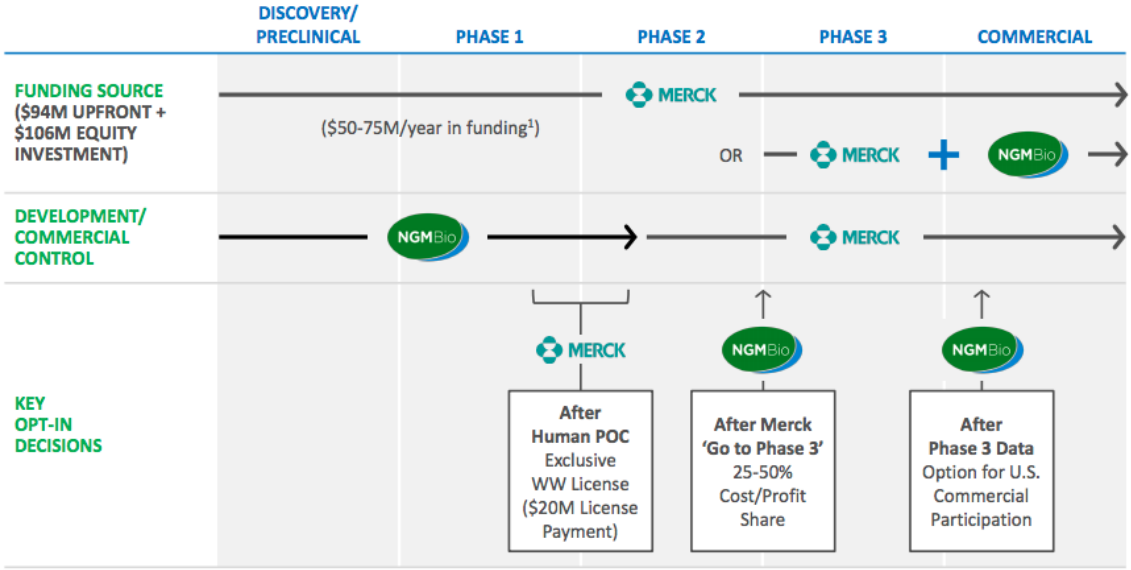
For example, as per NGM's filings:

"In 2015, we entered into a five-year research collaboration, product development and license agreement with Merck Sharp & Dohme Corp., or Merck. On March 15, 2019, Merck exercised its option to extend the collaboration for two additional years to March 2022. At inception, the collaboration included an exclusive worldwide license to our growth differentiation factor 15, or GDF15, receptor agonist program. On March 1, 2019, Merck notified us of its intent to terminate its license to the GDF15 receptor agonist program, effective May 31, 2019. Upon effectiveness of this termination, we will regain full rights to the GDF15 receptor agonist program, which includes NGM386 and NGM395. We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 study.

Under the collaboration agreement, we also granted Merck options to take exclusive, worldwide licenses for the programs in our research and development pipeline on a program-by-program basis. Merck generally has a one-time right to exercise its option when a program completes a human proof-of-concept trial. In November 2018, Merck exercised its option to license NGM313, an agonist antibody selectively activating fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, as a potential treatment for NASH

and type 2 diabetes. The collaboration enables us to develop more product candidates for major indications than we could likely advance on our own, with Merck bearing a majority of the associated cost and risk.

We retain an option, when a candidate has advanced to Phase 3 clinical trials, to participate in up to 50% of the economic return from that candidate if it becomes an approved medicine. Overall, the Merck collaboration provides us with robust research and development support, while we retain our research independence and the option to split costs and profits on product candidates Merck elects to advance. We excluded our fibroblast growth factor 19, or FGF19, program, including NGM282, from the agreement and it remains wholly-owned by us."



[1] Merck has committed to provide R&D reimbursement of up to $50 million per year. If our R&D expenses exceed $50 million in a given year, Merck can either reimburse up to an additional $25 million for use in funding IND-enabling or later-staged activities or to provide us with the equivalent value in in-kind services for such activities.

Let this be a lesson for those reading. It's important to look at situations like these, especially with pharmas because the exit strategy is extremely important and is arguably #1 if not #2 on what causes these stocks to skyrocket alongside an FDA approval.

When it comes to fundamentals, clinical stage pharmas are not really the best use case. As of March 31, 2019, cash, cash equivalents and short-term marketable securities were $193.4M which does not include the net proceeds from NGM's initial public offering and the private placement of shares with Merck, which closed in April of a total of $177.8M in additional cash. This puts cash somewhere around $370M, excluding Q2 cash burn, compared to $206.6 million as of December 31, 2018. As of Q1, operating cash flow burn was around $15.2M so that $370M or so should hold the company over for quite some time despite heading into some very important tests on NGM282.

Technical Analysis

NGM is a tougher stock to analyze technically because it's only been on the market for a few months. The stock has made a good climb off of the $13 level to get to the mid $14s here and as of right now the 50DMA of $14.38 will be an area of support followed by the 20DMA of $13.95. On RSI and W%R, the stock isn't overbought but it's beginning to hit those levels on the Money Flow Index. If the stock can break higher, the next resistance upwards is $14.86 followed by $15.67.

Overall, NGM does have a decent pipeline although not as far along as some of the other names mentioned. Companies operating in the NASH field are competing heavily against one another and it's nearly impossible to decide who will come out on top which is why it is usually best to spread your investment amongst different names to reduce risk. NGM282

looks like a product that could make some serious noise in the market alongside the continued support from Merck and the history of M&A with Goeddel. With that in mind, the company still has a long way to go before Phase 3 and whether or not they get the full-blown FDA approval is far too early to tell.

As with most clinical stage pharmas, the risk is high and based on the charts it seems investors are in a “wait and see” mode.