William Blair

Equity Research
Healthcare

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Private Company Spotlight

KLEO PHARMACEUTICALS

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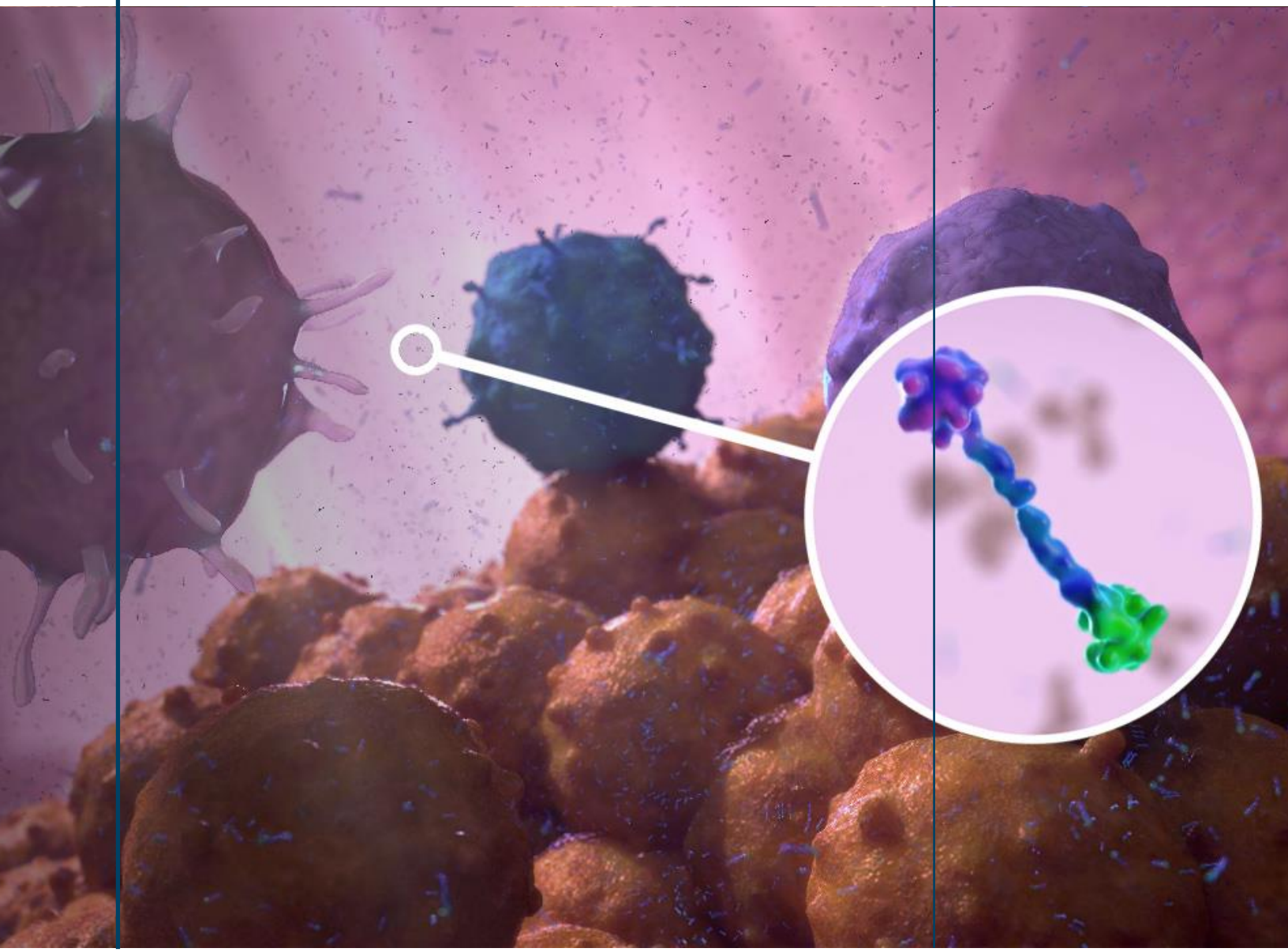

Please refer to important disclosures on pages 5-6. Analyst certification is on page 5.

KLEO PHARMACEUTICALS

Key Metrics

$34M
Venture funding raised to date

3
Proprietary technology platforms

3
COVID-19 programs

3
Partnerships with industry leaders

Investor Summary

biohaven pharmaceuticals

PeptiDream

connecticut innovations

Yale University

Kleo Pharmaceuticals, Unlocking the Versatility and Broad Applicability of Bispecific Small Molecules That Potentiate Endogenous IgG

Our Q&A With Doug Manion, M.D.

Chief Executive Officer and Chairman of the Board

1. Briefly describe Kleo's founding and approach?

Kleo Pharmaceuticals was founded in 2015 to develop synthetic molecules that redirect a patient's own immune system to target and destroy cancer, infections, and other intractable diseases. In his research at Yale University, Dr. David Spiegel, Kleo's scientific co-founder, championed the idea of designing synthetic drugs that function like biologics while maintaining the inherent advantages of small molecules including lack of immunogenicity, superior biodistribution, faster development times, greater market accessibility, and lower cost of goods. Leveraging his expertise in computational chemistry and knowledge of immunology, Dr. Spiegel developed and validated an early suite of small molecules known as ARMsTM (antibody recruiting molecules), which retargeted endogenous antibodies against a variety of oncology and non-oncology cell surface targets.

Dr. Spiegel then teamed up with Roy Prieb, Kleo's COO/CFO and co-founder, to formulate a business plan around this new platform technology. Together they won the inaugural Boehringer Ingelheim Innovation Prize, which facilitated Kleo's licensing of the ARM patent portfolio from Yale in 2016 and the series A equity financing led by Biohaven Pharmaceuticals. Since then, Kleo has expanded its technology portfolio through both internal R&D programs and partnerships with industry leaders including PeptiDream, Green Cross, and Celularity. The company's lead asset is KP1237, a CD38-targeting ARM, which is being developed for the treatment of multiple myeloma both in combination with NK cell therapies and as a monotherapy. The company has also developed a new technology, called MATEsTM monoclonal antibody therapy enhancers, which is being leveraged to develop a synthetic convalescent serum to treat COVID-19.

2. What should investors appreciate about Kleo's platform versus other companies looking to potentiate NK cell response?

Kleo's ARM technology *redirects endogenous immunoglobulin (IgG)* to disease targets, including tumor cells, viruses and micro-organisms such as fungi. This process, called opsonization, is the means by which a pathogen is marked for ingestion and destruction by phagocytes and NK cells, respectively. ARMs redirect IgG to targets not currently recognized by a patient's immune system. Compared to some monoclonal antibodies (mAbs) designed to engage NK cells (Fc-enhanced mAbs), ARMs offer several advantages including superior biodistribution, a lack of immunogenicity, which can lead to 30-60-fold higher dosing levels, and improvements in development time, manufacturing costs, and product distribution.

ARMs do not compete with other autologous and allogeneic NK cell platforms, but rather have been shown to synergistically enhance NK cell-directed immunotherapeutic approaches when used in combination. Other mechanisms of NK cell redirection in the clinic are the

abovementioned mAbs and chimeric antigen receptors (or CAR-NK). Compared to therapeutic mAbs, the ARM-IgG complex is proposed to opsonize the target cell at much higher levels due to the former's dose-level restriction. Compared to CAR-NK therapies, the lack of genetic engineering dramatically improves lateral expansion of a pipeline. One NK cell product can be used for unlimited applications. Perhaps most importantly, systemically administered ARMs may be more potent by recruiting both endogenous NK cells and macrophages in addition to the administered NK cell therapy.

3. What can you share about Kleo in terms of pipeline assets, stage of development, and key data sets or events you are looking forward to, in the next 12-24 months?
Our lead asset is KP1237, which is currently in development for the treatment of multiple myeloma. We are looking forward to multiple milestones around this asset in the next 12-24 months including:

Third Quarter 2020: Initiation of a Phase 1/2 clinical trial evaluating the safety and efficacy of KP1237-autologous NK cell combination therapy in post-autologous stem cell transplant patients

- **Third Quarter 2020:** Initiation of a Phase 1 study evaluating the safety of KP1237 in healthy volunteers. Completion of this study will allow a higher starting dose to be used in an upcoming Phase 1/2 trial of KP1237 in Darzalex® relapsed/refractory (R/R) patients.
- **First Quarter 2021:** Initiation of a Phase 1/2 trial evaluating the safety and efficacy of KP1237 in Darzalex® R/R multiple myeloma patients.
- **Second Half 2021:** Top-line data for the Phase 1/2 trial evaluating KP1237-autologous NK cell combination therapy in post-transplant patients

Additional assets include our COVID-19 ARM and MATE assets. We expect to achieve cellular proof of concept for each of these assets in third quarter 2020 and complete IND filings by first quarter 2021

4. Highlight some advantages of using small molecule/synthetic approach compared with peptide and biologic-based modalities?
Kleo's synthetic molecule platforms possess several inherent advantages over biologics. First, synthetic molecules are non-immunogenic and present a superior safety profile compared to their biologic counterparts. The body does not recognize them as a foreign protein and therefore doesn't mount anti-drug immune response against them. Second, synthetic molecules are much smaller than biologics and they can permeate and penetrate tissues better to reach their targets. Third, synthetic molecules are faster and cheaper to develop than biologics. By leveraging computational chemistry and the modular structure of its platforms, Kleo began generating compounds against SARS-CoV-2 Spike protein in a matter of weeks once the structure of the target had been established.

The ARM platform leverages these advantages to deliver a unique clinical approach. ARMs are designed to direct all endogenous IgG 1, 2, and 4 antibodies against a selected target. There are vast levels of these naturally occurring antibodies in the body, up to 50 more than the maximum level achievable by injecting a therapeutic antibody, and it is possible to safely dose ARMs at much higher levels than biologics; it is therefore possible to achieve much higher target saturation and greater efficacy without increased toxicity or financial burden.

5. Outline the rationale behind choosing CD38 as the first target.
There were two major factors behind our decision to pursue CD38 as the target for our lead program. First, CD38 is a clinically validated target, as Darzalex® (an anti-CD38 monoclonal antibody) is FDA approved for the treatment of multiple myeloma. Working with a validated target enabled us to more rapidly develop our technologies as it gave us a positive control to benchmark our platform's performance. Second, while a very successful commercial drug product, Darzalex® also has well-documented shortcomings that highlighted clinical opportunities where ARMs could be leveraged to address an unmet need.

Post autologous stem cell transplant patients, the target population of Kleo's upcoming Phase 1/2 clinical trial, are ineligible for Darzalex therapy due to its immunosuppressive side effects. The immunosuppressive effects of Darzalex are also believed to limit the efficacy of commonly used Darzalex-based combination treatments, as several Darzalex co-therapies rely on immunotherapeutic mechanisms of action. Additionally, Darzalex activates complement dependent cytotoxicity pathways, which leads to infusion reactions and patient resistance to treatment. Preclinical data show that KP1237 overcomes each of these shortcomings, highlighting its potential to supplant Darzalex as a best-in-class CD38-targeted therapy for multiple myeloma patients.

6. It appears that the company is expanding beyond oncology into infectious diseases, including targeting SARS-CoV-2. Tell us a little about that.

Once the pandemic began, we knew that the speed and modularity of Kleo's platform technologies would enable us to rapidly develop novel COVID-19 therapies and help lead the fight against the disease. We have been developing COVID-19-targeted ARMs and MATEs and have secured partnerships with Green Cross LabCell, Celularity, and the Bill & Melinda Gates Foundation to advance these programs into the clinic. The rapid progress we have made to date on these programs is a testament both to the inherent advantages of our technology platforms, but also to the depth of infectious disease experience of our CEO Dr. Doug Manion, a physician who was on the forefront of the HIV epidemic of the 1980s.

Under the leadership of Dr. Manion, Kleo is currently developing three COVID-19 programs.

(1) The first program, funded by the Bill & Melinda Gates Foundation, builds on the prior clinical success of COVID-19 hyperimmune globulin (COVID-19-HG) by creating a hyperimmune globulin mimic (HGM) via the chemical conjugation of COVID-19-targeting MATEs to IgG antibodies in healthy donor plasma. Like COVID-19-HG, HGM will target antibodies to sites of viral infection and facilitate the destruction of viral particles by immune cells. However, because HGM will be derived from healthy donors it will be much more scalable than COVID-19-HG, which must be harvested from donors that have previously been infected with SARS-CoV-2.

(2) Kleo's second COVID-19 program involves using a COVID-19 targeted ARM to direct immune cells to sites of viral infection. Such a strategy has the potential to work via three separate biological mechanisms:

- **Blocking the virus directly.** When ARMs are administered to a patient and reach the virus, they bind the spike proteins (at S1 and S2 domains), blocking the virus from binding the ACE2 receptor and infecting human cells. Kleo has already shown that a similar approach is effective in treating HIV.
- **Enlisting immune cells.** ARMs can, upon binding to the virus's spike proteins, recruit the body's immune cells to attack sites of viral infection. Immune cell (e.g., macrophages, NK cells) recruitment is facilitated by linking the SARS-CoV-2 spike protein to FcγRII-III immune cell receptors.
- **Activating long-term immunity.** Through a process similar to the one described above, ARMs can recruit dendritic cells to encourage the immune system to adapt to viral proteins. The immune memory cells (e.g., B-cells and T-cells) can then instill long-term immunity against the virus.

(3) Kleo is currently collaborating with Green Cross LabCell and Celularity on its third COVID-19 program, which aims to combine COVID-19-targeted ARMs with allogeneic NK cell therapies. When used in combination with NK cells, ARM bifunctional molecules behave similarly to chimeric antigen receptors by crosslinking infected cells and NK cells through binding to antibodies, but their synthetic nature eliminates the need for genetic engineering.

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DOW JONES: 26469.90
S&P 500: 3215.63
NASDAQ: 10363.20

Additional information is available upon request.

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