LEARN | DISCUSS | INVEST

CUBEWEALTH

ZAI LAB
EQUITY REPORT

JANUARY 21ST, 2020

ZAI LAB SUMMARY

BY THE NUMBERS

TICKER: ZLAB
PRICE: $53.10

Zai Lab Ltd. is a biopharmaceutical company that engages in discovering or licensing, developing, and commercializing proprietary therapeutics that address medical needs in the fields of oncology, infectious, and autoimmune diseases in China and internationally.

The company was founded in 2013 and is headquartered in Shanghai, China.

N/A	+104%	$3.5B
DIVIDEND YIELD	Y/Y RETURN	MARKET CAP

ANALYSIS

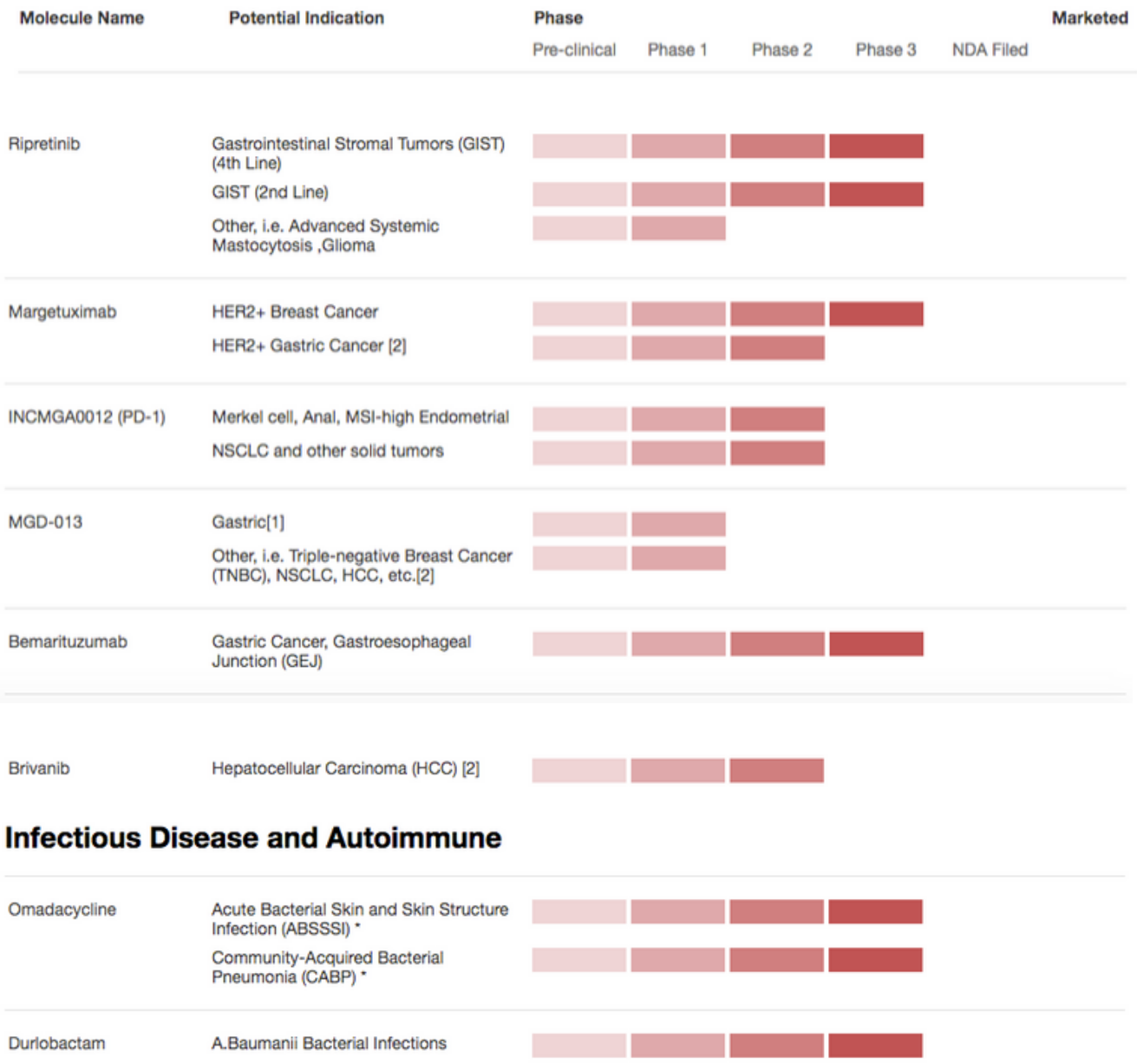
Zai Lab (ZLAB) is a pharmaceutical company that has had a terrific year in 2019 and has been off to a quick start here in 2020. The company has recently obtained additional approvals to launch their drugs in Hong Kong and Macau and have a pretty developed pipeline of drugs.

As with every pharma company we cover, let's analyze their pipeline. It is first broken up into two parts:

1. Oncology (the treatment of tumors)
2. Infectious Diseases and Autoimmune

Oncology

Molecule Name	Potential Indication	Phase					Marketed
		Pre-clinical	Phase 1	Phase 2	Phase 3	NDA Filed	
Niraparib	Ovarian Cancer (2nd line maintenance) */PK Study						Mainland China, HK & Macau (China)
	Ovarian Cancer (1st line maintenance)						
	Small Cell Lung Cancer						
	IO Combo in Gastric, Ovarian, Non Small Cell Lung Cancer (NSCLC)						
Tumor Treating Fields	Glioblastoma (GBM) *- Optune						Hong Kong (China)
	Mesothelioma*						
	NSCLC						
	Brain Metastases						
	Pancreatic Cancer						
	Ovarian Cancer						
	Gastric Cancer						



Oncology

- **ZEJULA®** (niraparib) is a highly potent and selective oral, once-daily small molecule poly PARP 1/2 inhibitor.
  - ZLAB is conducting clinical trials to evaluate niraparib in several indications, including ovarian cancer and small cell lung cancer.
  - In 2017, niraparib was approved by the FDA and EMA as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. In October 2018, niraparib was approved in Hong Kong (China) for adult patients with platinum-sensitive relapsed....

- ... high grade serous epithelial ovarian cancer who are in a complete or partial response to platinum-based chemotherapy, without the need of BRCA testing. In December 2018, the China National Medical Products Administration (NMPA) accepted the New Drug Application (NDA) for niraparib. In January 2019, the NDA was granted priority review status. In December 2019, the China NMPA approved the NDA for ZEJULA (niraparib) as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.

- **Optune** is a Tumor Treating Fields (TTF) delivery system that uses electric fields tuned to specific frequencies to disrupt cancer cell division, inhibiting tumor growth and causing affected cancer cells to die
  - Optune is currently marketed in the United States, the European Union, Switzerland, Japan, Hong Kong (China) and certain other countries/areas for the treatment of newly diagnosed or recurrent GBM (Glioblastoma - AKA the most aggressive cancer that begins within the brain).
  - In September 2018, they obtained an exclusive license to commercialize Optune® in mainland China, Hong Kong (China), Macau (China) and Taiwan region from Novocure, Inc. In addition to GBM, we will collaborate with Novocure on development activities for TTFields in multiple solid tumor indications.
  - At tested frequencies, TTFields do not seem to affect healthy cells. Mild to moderate skin irritation is the most common side effect reported.
  - VIDEO ON IT HERE
- **Margetuximab** is an investigational, Fc-optimized monoclonal antibody (mAb) that targets human epidermal growth factor receptor 2.
  - Designed to fight breast cancer
  - In February 2019, their partner MacroGenics announced positive results from its pivotal Phase 3 study

- **Ripretinib** is an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal stromal tumors (GIST), systemic mastocytosis, and other cancers.
  - Designed to treat gastrointestinal tumors
  - In June 2019, they obtained an exclusive license to commercialize ripretinib in mainland China, Hong Kong (China), Macau (China) and Taiwan region from Deciphera Pharmaceuticals.
- **INCMGA0012** is an investigational mAb that inhibits PD-1, currently being evaluated as a monotherapy in registrational trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer.
  - In July 2019, they obtained the rights to develop and exclusively commercialize INCMGA0012 in hematology and oncology in mainland China, Hong Kong (China), Macau (China) and Taiwan region.
- **Bemarituzumab** is an isoform-selective antibody with enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) in development as a targeted immunotherapy for tumors that overexpress FGFR2b.
  - They are collaborating with Five Prime Therapeutics to conduct a randomized, controlled Phase III clinical trial to evaluate bemarituzumab in combination with modified FOLFOX6 chemotherapy as a front-line therapy for the treatment of gastric and gastro-esophageal junction cancers
  - Their partner Five Prime Therapeutics paused enrollment in the fourth quarter of 2019 and will conduct an early futility analysis for the FIGHT trial by the first half of 2020.

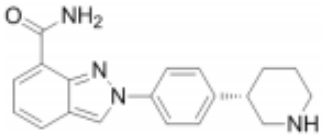
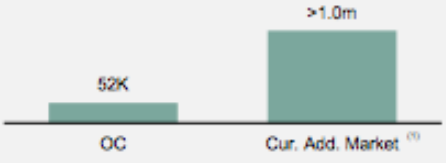
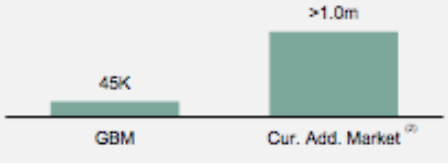
Infectious Diseases & Autoimmune

- **NUZYRA®** (Omadacycline) is a once-daily oral and intravenous antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

- Three pivotal Phase III studies of Omadacycline have achieved their respective primary endpoints.
- Omadacycline has been granted Qualified Infectious Disease Product (QIDP) status in the United States and Fast Track status by the FDA.
- In China, Zai lab received the approval from Chinese CDE (Center for Drug Evaluation) in July 2018 and is currently preparing the local clinical study.

- **Sulbactam-durlobactam** is a broad-spectrum and potent inhibitor of Class A, C, and D β-lactamases. This is a novel IV antibiotic for the treatment of infections caused by carbapenem-resistant Acinetobacter.
  - Designed for the treatment of hospital-acquired and ventilator-acquired bacterial pneumonia and bloodstream infections
  - Durlobactam has completed single/multi-ascending dose Phase I trials, and a Phase II study as well.
  - The FDA has granted Qualified Infectious Disease Product (QIDP) designation and Fast Track designation to Sulbactam-Durlobactam
  - In 2018, they obtained an exclusive license for Durlobactam from Entasis in mainland China, Hong Kong (China), Macau (China), Taiwan region, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia and Indonesia. And in the Philippines, Singapore, Australia, New Zealand and Japan, we entered into a global strategic development collaboration with Entasis.
  - They are currently working closely with Entasis to prepare the Phase III study and to bring this drug into China as soon as possible.

All in all, what does this mean? It means that ZLAB, despite not having a pipeline like that of giant biotechs with 50 products, is moving along well on their phases. Of the 10 drugs they have, 7 are in Phase 3 and 2 of those are approved and being marketed which we find quite impressive.

	ZL-2306 (Niraparib)	Optune
		
Positioning/ Strategy	• **Best-in-class PARP franchise**	• New, breakthrough cancer treatment modality for multiple tumor types • **1st novel GBM treatment** in ~15 years
China Market Opportunity *(Annual Incidence in 2018E)*		
China Regulatory Status	• **Approved in HK and launched (Q4 2018)** • **NDA accepted by NMPA (Dec 2018)** • **Priority Review (Jan 2019)** • **Category 1 drug** • Local manufacturing	• **Launched in HK (Dec 2018)** • **Pursue clinical trial waiver in China** • Recommended in China Glioma guidelines based on Level 1 evidence

Competition

Lynparza®
olaparib
tablets 150 mg

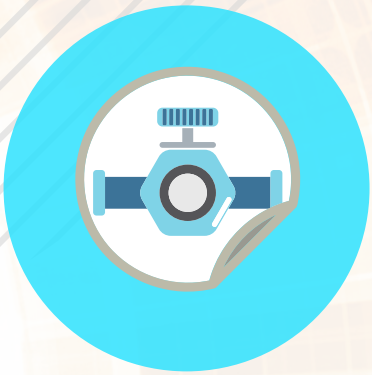
Rubraca®
(rucaparib) 300 mg tablets

EMulate
THERAPEUTICS

AtraZeneca's Lynparza sales in the first half of 2019 were $520M, representing growth of 93%, driven by expanded use in the treatment of ovarian and breast cancer in the US and Europe. The performance included growth in Emerging Markets of 228% to $59M and growth in Japan of 480% to $58M.

Clovis Oncology's Rubraca has seen $104M in sales three quarters through the year. In Q3, they saw $37.6M in net product revenue for Rubraca, up 65% Y/Y

CUBE'S TOP PROS FOR ZLAB



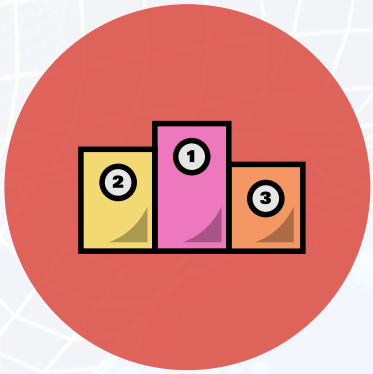
DEVELOPING PIPELINE

REVENUES ONBOARDED

LARGE MARKET

CUBE'S TOP CONS FOR ZLAB

CONCENTRATED PIPELINE

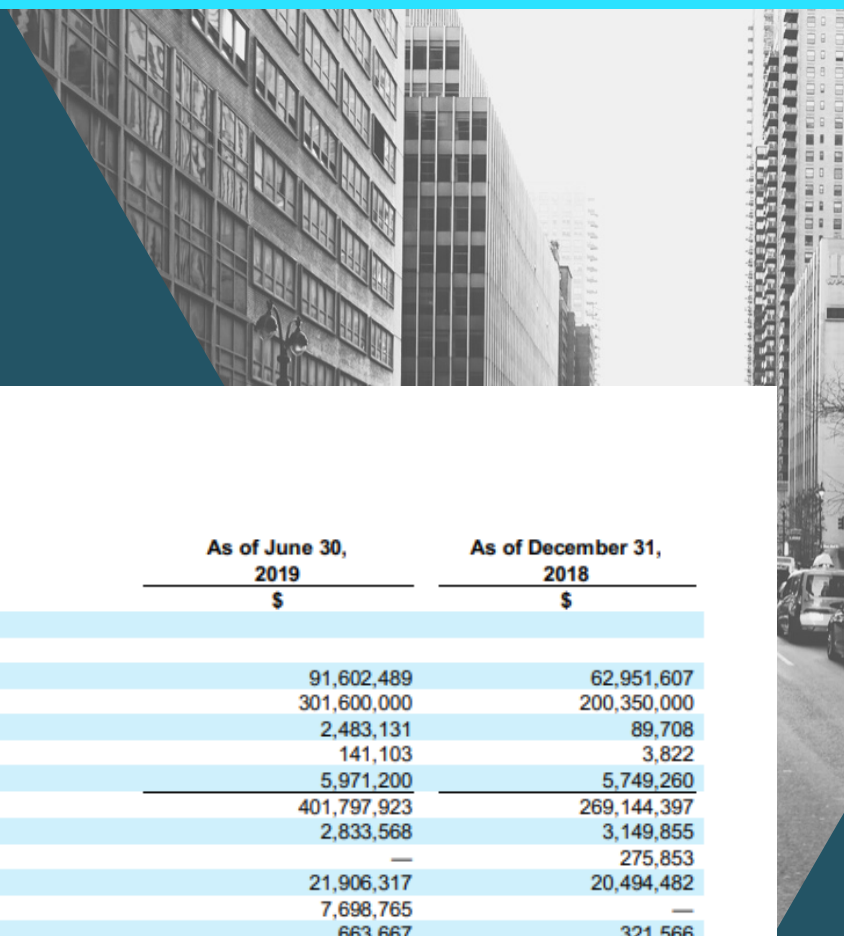


COMPETITION

CASH BURN

FINANCIAL STATEMENTS

BALANCE SHEET



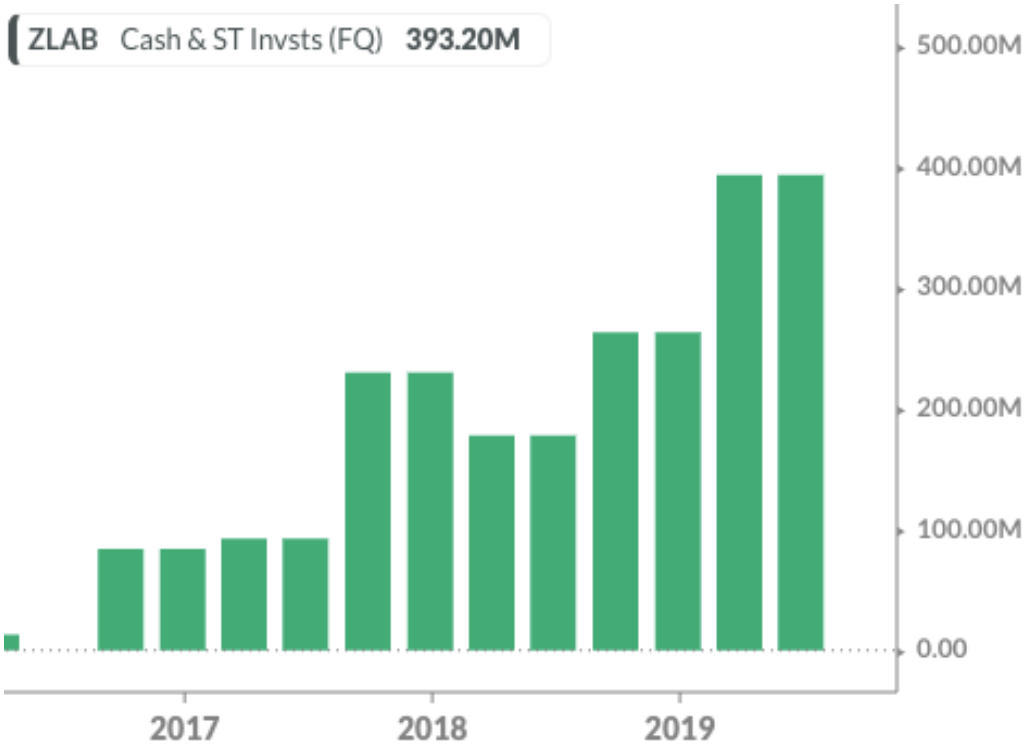
(In U.S. dollars ("$") except for number of shares)

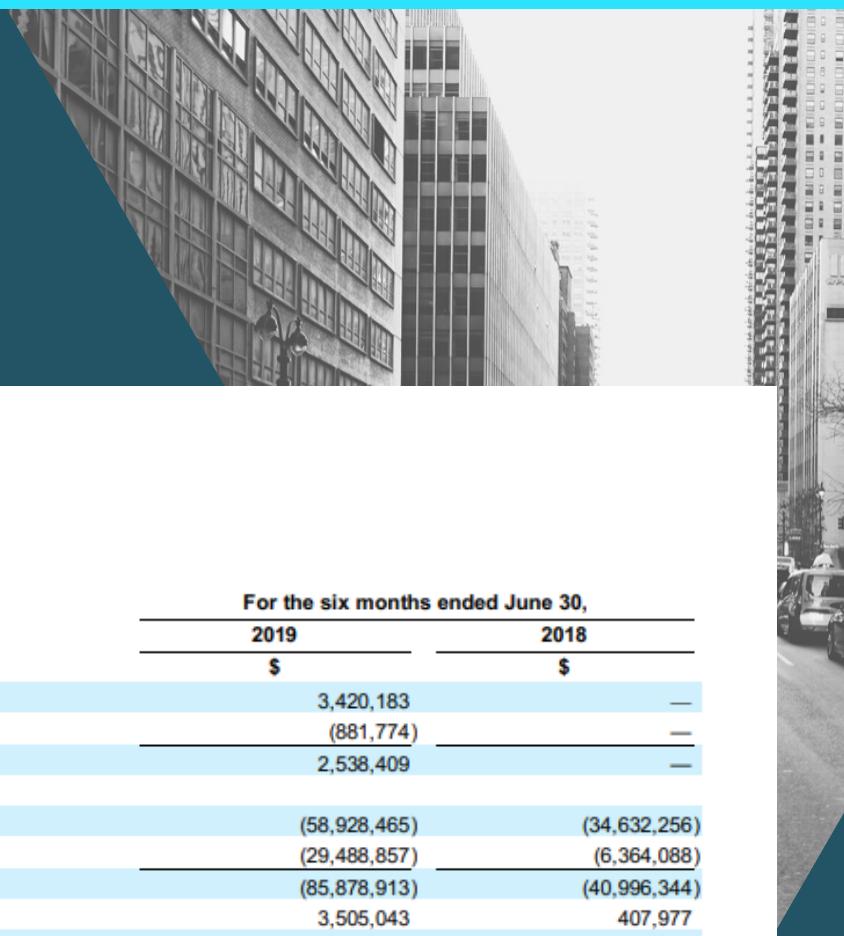
	As of June 30, 2019 $	As of December 31, 2018 $
Assets		
Current assets:		
Cash and cash equivalents	91,602,489	62,951,607
Short-term investments	301,600,000	200,350,000
Accounts receivable	2,483,131	89,708
Inventories	141,103	3,822
Prepayments and other current assets	5,971,200	5,749,260
Total current assets	401,797,923	269,144,397
Investments in equity investees	2,833,568	3,149,855
Prepayments for equipment	—	275,853
Property and equipment	21,906,317	20,494,482
Operating lease right-of-use assets	7,698,765	—
Intangible assets	663,667	321,566
Long-term deposits	389,773	556,738
Value added tax recoverable	11,170,490	8,044,258
Total assets	**446,460,503**	**301,987,149**
Liabilities and shareholders' equity		
Current liabilities:		
Short-term borrowing	5,818,436	3,642,616
Accounts payable	27,725,527	37,432,035
Current operating lease liabilities	2,899,075	—
Other payables	9,526,288	7,766,843
Total current liabilities	45,969,326	48,841,494
Deferred income	2,514,473	2,063,942
Non-current operating lease liabilities	4,646,586	—
Total liabilities	**53,130,385**	**50,905,436**
Total shareholders' equity	**393,330,118**	**251,081,713**
Total liabilities and shareholders' equity	**446,460,503**	**301,987,149**

When we look at ZLAB's balance sheet, it looks very similar to most pharma companies before they generate any meaningful revenues. The company is currently sitting on approximately $393.2M in cash equivalents and short-term investments.

This amount includes net proceeds of $216.2M obtained in a secondary offering that took place in May 2019. At ZLAB's current cash burn of around $200M per year, we'd say there's room for one more offering in Q3/Q4 of 2020 if revenues aren't generated swiftly enough.

CUBE also says this because now that ZEJULA and Optune are beginning to generate revenue, ZLAB will have to allocate more money on marketing and on top of this they aren't going to wait until cash is almost zero. For example, they raised $216M when there was still approximately $175M still on hand. As we can see from the image below, ZLAB has been boosting their cash on hand since going public in 2017. They did a secondary offering for $150M in September 2018, one year after going public, and now this one in May 2019. If history is any indicator, we should expect another offering in June 2020.





FINANCIAL STATEMENTS

INCOME STATEMENT

(In U.S. dollars ("$") except for number of shares)

	For the six months ended June 30,	
	2019	2018
	$	$
Revenue	3,420,183	—
Cost of sales	(881,774)	—
Gross profit	2,538,409	—
Operating expenses:		
Research and development	(58,928,465)	(34,632,256)
Selling, general and administrative	(29,488,857)	(6,364,088)
Loss from operations	(85,878,913)	(40,996,344)
Interest income	3,505,043	407,977
Interest expense	(276,768)	—
Other expenses, net	(320,258)	(695,618)
Loss before income tax and share of loss from equity method investment	(82,970,896)	(41,283,985)
Income tax expense	—	—
Share of loss from equity method investment	(302,827)	(206,443)
Net loss	(83,273,723)	(41,490,428)
Net loss attributable to ordinary shareholders	(83,273,723)	(41,490,428)
Loss per share - basic and diluted	(1.37)	(0.83)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	60,919,842	50,041,672

ZLAB reports their revenues twice per year. In the first half of 2019, the company posted their first revenues from ZEJULA and Optune to the amount of $3.4M. This isn't much for a $3.5B company but this is a watermark time period for them because it's actual revenue from a product and its compared to zero revenues in the same period the year prior.

Now there's something important to highlight here. ZLAB has a licensing right to market ZEJULA in Hong Kong, China, and Macau from Tesaro. GlaxoSmithKline GSK) acquired Tesaro for $5.1B at the end of 2018, which means ZLAB owes royalties to GSK now.

Takeda Pharma (TKPHF) also has a licensing agreement for Zejula (Niraparib) from Tesaro in 2017, now GSK, in Japan, Korea, Taiwan, Russia and Australia.

As per the SEC filings, under the terms of the agreement, ZLAB made an upfront payment of $15.0 million to Tesaro. If they achieve a specified regulatory, development and commercialization milestones, they may be required to pay aggregate milestone payments up to $39.5 million to Tesaro. In addition, if they successfully develop and commercialize the licensed products and Tesaro does not exercise its co-promotion option, they will pay Tesaro tiered royalties at percentage rates in the mid- to high-teens on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

This type of setup is pretty common in the pharma industry and we just wanted to bring to light that ZLAB did not develop this drug themselves. They owe Tesaro, now GSK, when ZEJULA sells. The point here is also that ZLAB will not be seeing the highest of margins on their product sales early on because milestone payments and royalties will be due to the respective parties. On top of paying GSK for ZEJULA, ZLAB will also have to pay Paretek for Omadycylcine.

Under the terms of the agreement, ZLAB made an upfront payment to Paratek Bermuda Ltd. of $7.5M and may be required to pay milestone payments up to $54.5M to Paratek Bermuda Ltd. for the achievement of certain development and sales milestone events. In addition, they will pay to Paratek Bermuda Ltd. tiered royalties at percentage rates in the range of low- to mid-teens on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

In addition, ZLAB will have to pay Bristol-Myers Squibb for Brivanib. If BMS does not exercise its co-promotion option, they may be required to pay BMS milestone payments up to $114.5 million for the achievement of certain development and sales milestone events, and also tiered royalties at percentage rates in the mid- to high-teens on the net sales of the licensed products in our licensed territory, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the twelfth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

This continues for several of their products and we just wanted to make sure it was known so when the payments are made you are not caught off guard.

SOME OTHER KEY STATS

Goal for Cancer Survival Growth

15%

"Healthy China 2030" is a goal to increase the overall five year survival rate of cancer by 15% by 2030. Going forward, innovative patented therapeutics are projected to grow at over 10% annually until 2020, which is expected to surpass the growth rate of generic products

China Pharma Market 2026

$237B

China's pharmaceutical market is the second largest pharmaceutical market in the world and is projected to grow from $115B in 2016 to $160B by 2021 and $237B by 2026

Breast Cancer in China

279K

The breast cancer treatment is ~279,000 cases per year in China, similar to the United States

Percent of Gastro, Lung, and Liver Cancer in China vs. World

40-50%

For some specific tumor types, including lung, gastric and liver, China's incidence represents approximately 40% to 50% of worldwide incidences.

ZLAB FUNDAMENTALS

Unfortunately there aren't any revenues that can be derived from ZLAB. The company doesn't have enough sales to generate a P/S multiple and it is far too difficult to estimate what revenues will be next year because of how new the drugs are in China, Macau, and Hong Kong. According to Seeking Alpha and Koyfin, analysts are expecting around $84M in revenue in 2020 with the lowest expectations coming in at $34M and the highest coming in at $213M.

Truth be told, fundamental analysis for an emerging pharma company hold little-to-no weight as the company is being valued on the drugs in their pipeline and revenues much further down the road.

CUBE would also argue that there isn't even a competitor close enough to compare them too because they are focused on the Chinese market and their competitors like AstraZeneca have a world of drugs in their pipeline and are much larger and more mature than them.

One thing we can deduce is that GSK had no issue purchasing Tesaro for $5.1B so that must mean they have big expectations for Zejula worldwide. As we saw above, AstraZeneca's Lynparza is seeing insane growth worldwide as is Clovis.

The same should apply to ZLAB considering the favorable statistics in China.

ZLAB FUNDAMENTALS

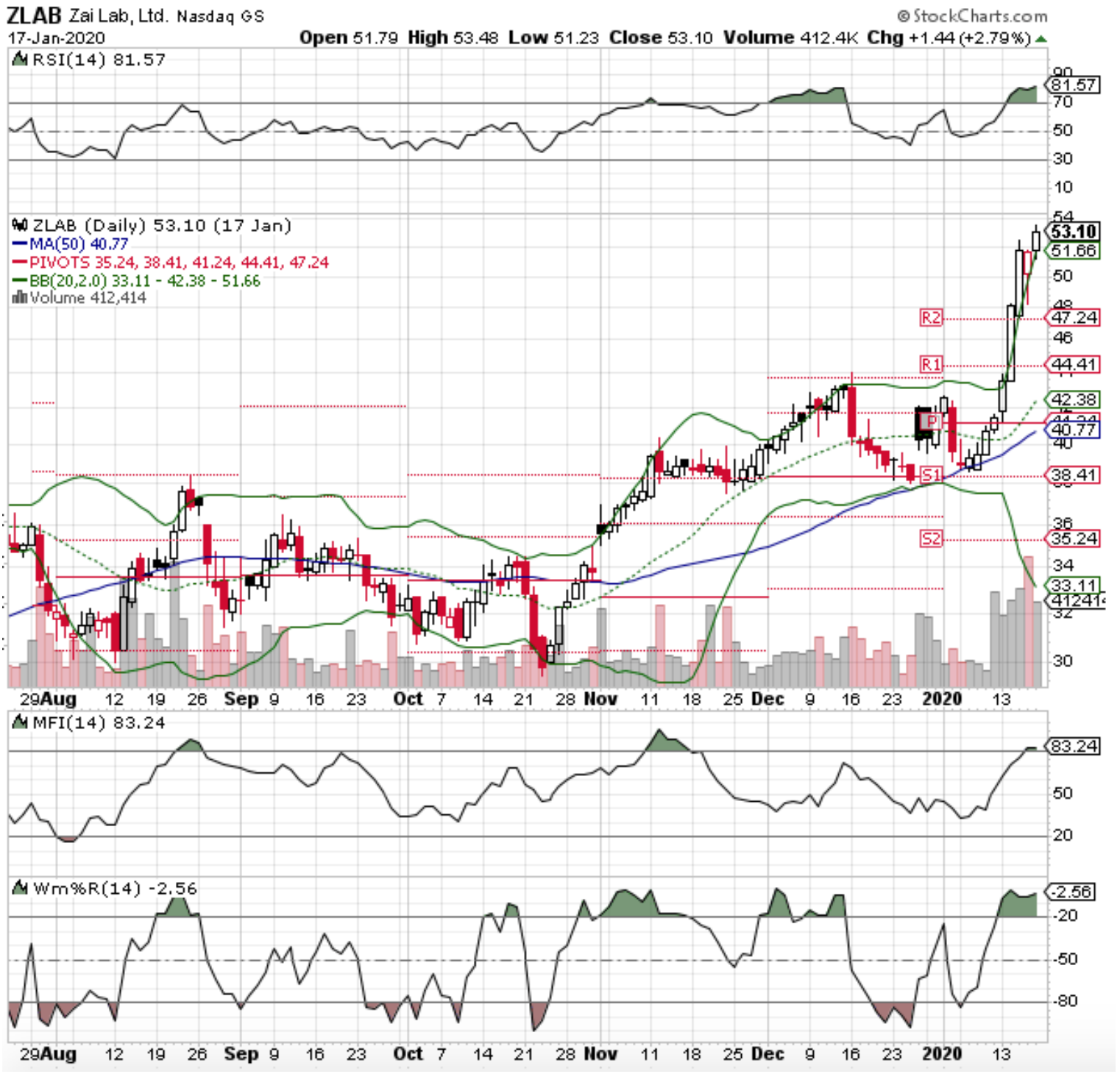
On top of the Breast cancer stat previously mentioned, Ovarian cancer had an estimated annual incidence of 52,000 patients in China in 2015, which is more than double that of the 21,300 patients in the United States and has seen increasing mortality rates.

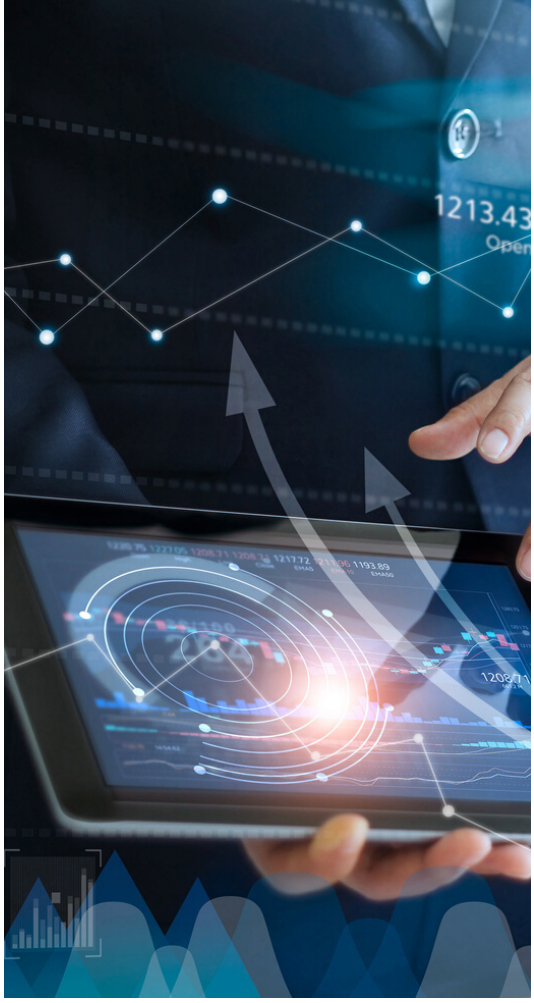
Lung cancer has the highest total incidence as well as the highest mortality rate of any cancer in China. Annual incidence was estimated at 733,300 patients in China in 2015, which is more than triple the 221,200 patients in the United States.

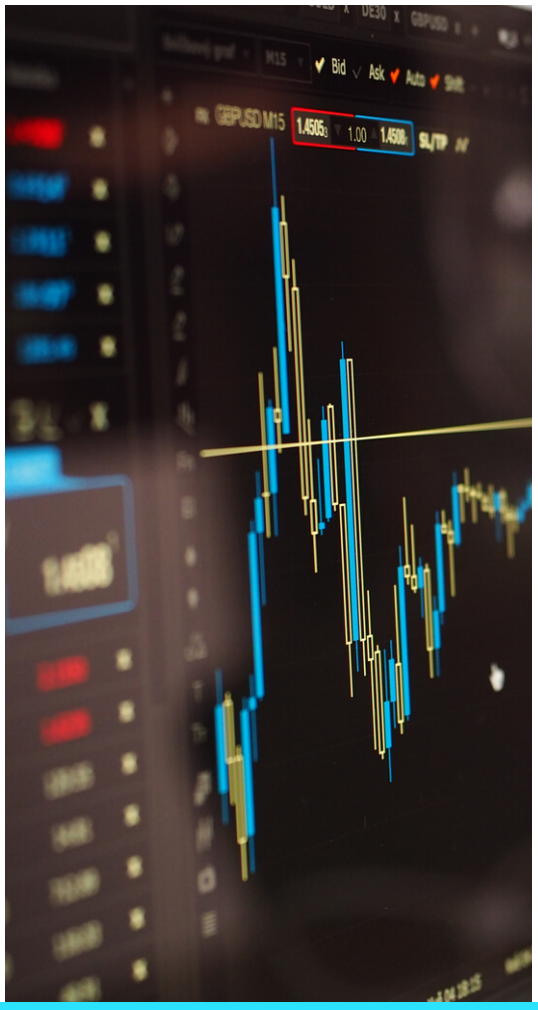
According to the American Cancer Society, approximately 80% to 85% of lung cancers are non-small cell lung cancer and squamous cell carcinoma is about 25% to 30% of lung cancers. Based on an assumption of 80% share of non-small cell lung cancer and 30% of cancers being squamous, ZLAB estimates a potential target patient population of 176,000 patients with squamous-type non-small cell lung cancer and 147,000 in small cell lung cancer in China.

While unfortunate, it's safe to say there is a huge market for ZLAB to explore.

ZLAB
TECH ANALYSIS







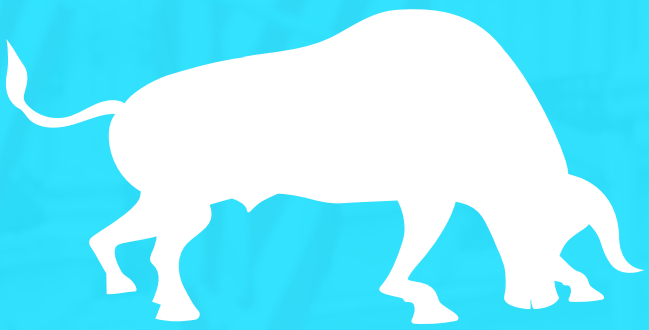
TECH ANALYSIS SUMMARY

As we noted earlier, ZLAB has skyrocketed recently due to getting the thumbs up from China's National Medical Products Administration for ZEJULA on recurrent ovarian cancer.

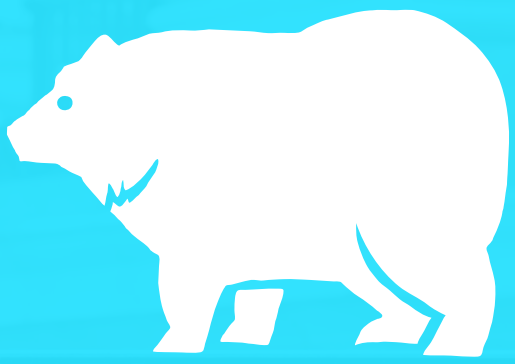
The stock has broken past all major resistance levels but we do feel shares have gotten a little carried away at the moment. We expect shares to pull back within their bollinger band of $51.66 in the short-term as major metrics like that of the RSI, MFI, and W%R are all indicating it is overbought.

Considering this move is based on news and fundamentals of government approvals, we expect a short-term pullback, consolidation around the R2 level in the high $40s and low $50s, followed by another move higher as ZLAB posts their 2H19 results - if, of course, sales are starting to really ramp. If not, it will be difficult for ZLAB to hold a $3.5B market cap.

BULLISH OR BEARISH?



VS.

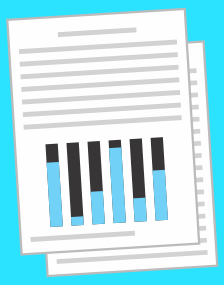


MORE BULLISH (POSITIVE)

MORE BEARISH (NEGATIVE)

cube

LEARN | DISCUSS | INVEST



ZLAB CONCLUSION

Overall, CUBE is positive on Zai Lab (ZLAB). We feel in the short-term shares can pullback but the company is finally starting to onboard revenues from their major products and is tapping into an industry that statistics show is in deep need of help.

With revenues seemingly ramping up things are looking bright for ZLAB but because of the payout and royalties that are due we anticipate another secondary offering here in 2020 which would dilute shares one more time.

While ZLAB's pipeline is not the largest or most diversified, it does have some nice approvals already locked in which could create even more revenue streams in 2021 and beyond especially with the growing market in China.

Some notable risks are that competition is growing and there are always uncertainties in healthcare, especially in an emerging market like that of China. These are areas that must be watched closely because a medicine is only as good as how easily it can be obtained, marketed, and distributed.

DISCLAIMER

NOTHING IN THIS DOCUMENT, OR ANY DOCUMENTS FOR THAT MATTER, SHOULD BE USED OR CONSTRUED AS AN OFFER TO SELL, A SOLICITATION OF AN OFFER TO BUY, OR A RECOMMENDATION FOR ANY SECURITY. NOR IS IT INTENDED AS INVESTMENT, TAX, FINANCIAL OR LEGAL ADVICE. INVESTORS SHOULD SEEK SUCH PROFESSIONAL ADVICE FOR THEIR PARTICULAR SITUATION. CUBE DOES NOT MAKE ANY GUARANTEE OR OTHER PROMISE AS TO ANY RESULTS THAT MAY BE OBTAINED FROM USING OUR CONTENT. NO ONE SHOULD MAKE ANY INVESTMENT DECISION WITHOUT FIRST CONSULTING HIS OR HER OWN FINANCIAL ADVISOR AND CONDUCTING HIS OR HER OWN RESEARCH AND DUE DILIGENCE. TO THE MAXIMUM EXTENT PERMITTED BY LAW, CUBE DISCLAIMS ANY AND ALL LIABILITY IN THE EVENT ANY INFORMATION, COMMENTARY, ANALYSIS, OPINIONS, ADVICE AND/OR RECOMMENDATIONS PROVE TO BE INACCURATE, INCOMPLETE OR UNRELIABLE, OR RESULT IN ANY INVESTMENT OR OTHER LOSSES. CONTENT CONTAINED ON OR MADE AVAILABLE IS NOT INTENDED TO AND DOES NOT CONSTITUTE LEGAL ADVICE OR INVESTMENT ADVICE AND NO ATTORNEY-CLIENT RELATIONSHIP IS FORMED. YOUR USE OF THE INFORMATION IS AT YOUR OWN RISK. THIS CONTENT IS CONFIDENTIAL AND MUST NOT BE DISTRIBUTED