

July 26, 2018

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## BeiGene, Ltd. (BGNE US)

# China Builds Resistance to Cancer Drugs

### ▶ **Just never going to sell those drugs**

Much hope surrounds the Chinese cancer-drug market, following the lowering of import barriers, removal of taxes, and fast-track clinical trial approvals. But we estimate that foreign cancer drugs get no more than 3% of global revenues from China even years after approval. And our interviews with regulators, SOE drug companies, and hospitals confirm that Chinese regulators are determined not to permit high-priced cancer drugs to be widely reimbursed. And now, the premier has reiterated that cancer drugs need to be cheap. That will ensure voices to the contrary are stifled.

### ▶ **Where's the founder's confidence?**

John V. Oyler has sold \$122 mln in stock. That doesn't say a lot for his confidence in the company's future.

### ▶ **Unneeded manufacturing**

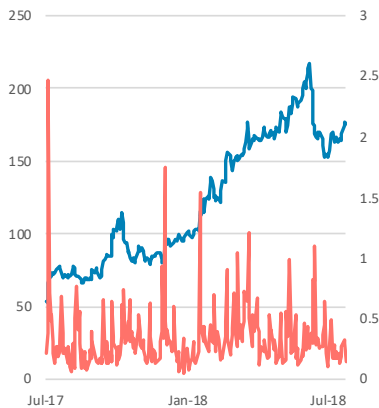
BeiGene is building a biologics facility in Guangzhou at the behest of that government. The company also has a facility in Suzhou. These facilities, we believe, add to Chinese over-capacity and add to the management strain of operating a company doing drug development, contract development, manufacturing, and marketing and sales, without institutional experience in anything but development. We think the lack of focus is damaging, and we believe the capex, being done more to placate regulators than for sound corporate reasons, will continue to mount.

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### BeiGene Ltd. (BGNE US)

Share Price	\$ 175.95
<b>J Cap's Valuation</b>	<b>\$ 71.61</b>
Market Cap (mln)	\$ 9,456.4
Difference	-59%
Price/Sales	35x

BeiGene (BGNE US) last share price in usd (blue, left) and volume (green, right, mln shares)



Source: Bloomberg July 25, 2018

#### ▶ Pumping hard

BeiGene has filed for a dual listing in Hong Kong. That IPO could send the shares higher. This very promotional company is pushing out positive news as fast as it can.

#### ▶ Overvalued

We model BeiGene's performance based on the history of blockbuster cancer drugs in China rather than on the notional need for cancer drugs. We apply a DCF model with an 8.4% WACC and 2.5% terminal growth rate and come to \$71.61 on a DCF. Using a multiple of 18.5x 2022 Ebitda, alternatively, with no discount, we come to \$90. We are comfortable estimating that BeiGene is 60% overvalued.

#### ▶ Watch the risks

BeiGene is a short to trade in and out of, not to hold, until the market starts to care about fundamentals. Risks are that Celgene will buy the company at a stupid valuation, that the PARP inhibitor drug will be licensed by a major and will excite the market, and that there will be a successful debut in Hong Kong.

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BeiGene is the market's greatest hope for biotech in China. Trading at \$175, the shares are down from their June peak of \$217 but up from the \$24 IPO price in just two and a half years. BeiGene does its own drug development but also has a hand in manufacturing and contract sales just in case. With a bit of revenue from selling Celgene drugs in China and a lot of excitement over a narrow pipeline of me-too drugs, BeiGene attracts fervid enthusiasm for the drugs it maybe might launch in a year or two. The company is highly promotional, and management appears to know that the delirious valuation will not last forever; the chairman has sold \$122 mln in stock before BeiGene has managed to spit anything out of the pipeline.

We do not believe the company is worth the hype. Even assuming perfect execution, inclusion in the national drug reimbursement list within China for BeiGene's three pipeline drugs, good sales growth for the Celgene drugs it represents, and a 15% royalty on overseas sales of a successful PD-1 drug, we cannot value BeiGene at more than half its current level.

Furthermore, we think the market has not yet absorbed the Chinese premier's recent comments that underscored China's policy of making cancer drugs cheap and restricting access to high-priced drugs. When it does, BeiGene's valuation is likely to become more earthbound.

### Basics

BeiGene has several business lines:

- ▶ The company has three principal drugs under development:
  - Zanubrutinib: a Bruton's tyrosine kinase (BTK) inhibitor very similar to AbbVie's Imbruvica (ibrutinib), for treatment of mantle cell lymphoma. Zanubrutinib, if trials go well, could be commercialized next year.
  - Tislelizumab: A PD-1 drug for Hodgkin's lymphoma. Earliest commercialization is two years off .
  - Pamiparib: A PARP inhibitor several years from commercialization
- ▶ Agency sales in China of Celgene's international blockbuster drugs Revlimid, Abraxane, and Vidaza. Combined sales of these drugs in Q1 2018 amounted to \$23.5 mln, BeiGene reported.
- ▶ Contract manufacturing: The company has three manufacturing facilities: a factory in Suzhou for small-molecule drug candidates and pilot-scale biologics, a small facility in Beijing making clinical trial materials, and, under

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“Expensive drugs simply have no significant market in China.” – Chinese drug regulator

construction in Guangzhou, a large facility for biologics.

- ▶ Licensing agreements: The company has fairly small-scale licensing agreements with Merck, Mirati Therapeutics in Asia, and Celgene in China.

Hopes for this company’s profitable future lie with the pipeline drugs. BeiGene’s pitch to investors is that the company has a top-flight international team but is born and bred in Beijing and has unique access to the China market. The “we understand China” comments are sprinkled throughout company communications. Company founder John V. Oyler said at a Cowen Healthcare conference March 7, 2017: “While we’re a global oncology player, we’re also uniquely positioned to create value in China. We’re set up as a company that can approach China as a local organization and this enables us to take advantage of the structural features in China that are advantageous for local companies.” In May this year, CFO Howard Liang said at a Deutsche Bank conference: “I think fundamentally, we have two main business areas that we operate in. One is, we’re a China-based company where the intention is . . . to build the leading biotech company in China, where there is a lot of opportunity waiting as the country develops its healthcare system at the health -- the drug -- from clinical market develops. . . The other aspect is the -- we are a biotech company with an internally developed differentiated asset.” BeiGene tells the market that it is the biotech play for China, a company with unique local understanding that does not compromise on quality.

But, international or Chinese, pharmaceutical companies have not been able to achieve volume sales for new, expensive drugs in China. The Chinese market may be huge, but time has shown that the market is accessible to eye drops, aspirin, cold medicines, health supplements, and folk cures of all kinds but not to new drugs with expensive R&D costs behind them.

We looked at eight cancer drugs that are licensed for sale within China and estimated their sales value in China based on annual reports, conference calls, and other company information. Information is sparse, but as far as we can tell, China represented about 2% of international sales for these drugs several years after the drugs entered the market.

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**Table 1. Estimated China Sales of Cancer Drugs (mln USD except for Bayer, mln EUR)**

Drug	Producer	Drug class	Global Revenue	Non-US Revenue (USD mn)	China Revenue	China % of revenue	Revenue year	Source note
<b>IMBRUVICA</b>	AbbVie/ Janssen (JNJ)	Cancer, blood (including mantle cell lymphoma, chronic lymphocytic leukemia, Waldenstrom's macroglobulinemia)	1,893	252	10	1%	2016	AbbVie 2017 10-K
<b>Revlimid</b>	Celgene	Cancer, blood (multiple myeloma)	8,187	2,761	65	1%	2018 E	CELG 2017 10-K, BeiGene Q1
<b>Vidaza</b>	Celgene	Cancer, blood (multiple myeloma)	628	620	0	0%	2017	BeiGene Q1
<b>Pomalyst/ Imnovid</b>	Celgene	Cancer, blood (multiple myeloma)	1,614	606	0	0%	2017	
<b>Stivarga</b>	Bayer	Cancer, solid (colon, rectum, liver)	315	149	0	0%	2017	approved end of December 2017
<b>Abraxane</b>	Celgene	Cancer, solid (including breast, lung, and pancreatic cancer)	992	385	20	2%	2018 E	estimated: BeiGene Q1 cal
<b>Sutent</b>	Pfizer	Cancer, solid (including kidney, pancreas, and intestinal)	1,081	707	99	9%	2017	<a href="#">Pfizer Inc. Revenue 2016/17</a>
<b>Inlyta</b>	Pfizer	Cancer, solid (kidney)	339	213	30	9%	2017	<a href="#">Pfizer Inc. Revenue 2016/17</a>
<b>Nexavar</b>	Bayer	Cancer, solid (kidney, liver, and thyroid)	834	540	50	9%	2017	<a href="#">Bayer Annual Report 2017</a>
<b>Xalkori</b>	Pfizer	Cancer, solid (lung)	594	371	52	9%	2017	<a href="#">Pfizer Inc. Revenue 2016/17</a>
<b>Lupron</b>	Abbvie	Cancer, solid (prostate)	829	160	n/a	n/a	2016	
<b>Xofigo</b>	Bayer	Cancer, solid (prostate, radiotherapy)	408	166	15	4%	2017	<a href="#">Bayer Annual Report 2017</a>
<b>AVERAGE</b>		Total	16,885		341	2%		

\* Values are estimates only. They are based on company disclosures of sales in emerging markets and an estimate of China's proportion of pharmaceutical sales in emerging markets.

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**The China Market: Dying to Survive**

Much has been made recently of China’s increased market opening to foreign drugs. In 2017, 15 cancer drugs were added to the catalog of medication covered by public health insurance, and, beginning May 1, 2018, China removed import tariffs on cancer drugs and reduced value-added tax from 17% to 3%. But these moves have been more than matched by administrative measures to lower the price of innovative drugs and tightly restrict national insurance coverage. China has a history of disappointing sales for expensive drugs, and all indications point to a decline, not increase, in sales of expensive drugs within China.

In July, the hit film “Dying to Survive” has held the top box office slot in China, reminding viewers of the true story of a cancer patient who smuggled drugs from India to help other leukemia patients in China. A year ago, under public pressure, the government of Hunan Province dropped a lawsuit against Lu Yong, a leukemia patient who helped more than 1,000 fellow sufferers buy a cheap generic cancer drug from India. In the film, the smuggler grows wealthy from his business but has a change of heart when he sees how the families of cancer patients have been driven into poverty by the costs of treatment. In mid-July, Premier Li Keqiang in praised the film and said that Chinese regulators must “speed up price cuts for cancer drugs” and “reduce the burden on families.” The comments echoed a promise by China’s minister of the National Health and Family Planning to bring down the cost of several trademarked drugs and to fast track the importation of drugs used to treat 20 kinds of critical illnesses.

The U.S. National Institutes of Health [has calculated](#) that median prices for cancer drugs in China are the second-highest in the world in absolute terms, after the United States, and, in Purchasing Power Parity terms, second only to India.

Over and over, Chinese regulators have emphasized that cancer drugs need to be cheap. We recently conducted five lengthy interviews with three drug regulators, a hospital director, and the sales director of a large state-owned pharmaceutical company in China, and every one said they believed high-priced cancer drugs would never achieve significant sales in the China market.

- ▶ The director of the Health Insurance Fund department of a provincial office of the Ministry of Human Resources and Social Security said, “You can’t say ‘expensive medicine’ and ‘high sales volume’ together in one sentence. China right now cannot support that type of market.” This regulator went on to say that expensive cancer drugs really have no chance of getting onto the national reimbursement list: “It’s very hard for a medicine to get on the national reimbursement list,” he said, “especially now. Basically, the list is fixed and is not growing. . . . In 2017, 36 medicines got onto the list after

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“The first responsibility of the health administration is to protect the integrity of the Health Insurance Fund.” – Chinese drug regulator

negotiations.” The 36, he said, included cheap medicines and expensive imported cancer drugs, but patented Western drugs that sell at comparatively high prices were required to cut prices by an average of 70% in order to get on the reimbursement list. Even so, he said, doctors are loathe to prescribe the expensive drugs, he said, and getting a drug onto the reimbursement list does not mean that it is easy to buy. For example, the insurance system will pay for drug treatment for post-operative patients with HER-2 positive breast cancer for only 12 months, and, even then, many certifications are required before the insurance will pay.

- ▶ Another regulator said that new drugs being developed now are targeting smaller populations, and pharmaceutical companies are raising prices to recover R&D costs. He said that the Chinese system would not accept these high prices and that drug companies need to figure out how to change their strategy.
- ▶ “Expensive imported medicines have no chance of sales growth, especially for cancers.” said the head of a large hospital in Hebei Province. “The national health insurance fund is not equipped to take on such high costs.”
- ▶ The sales director of a large State-owned pharmaceutical company agreed with this assessment. He also pointed out that the most significant cost for domestic drug-makers is not R&D but “facilitation fees” to achieve volume sales. He said the bribes have to be paid from the top to the bottom of the hospital, and that these fees cripple the profitability of expensive, low-volume drugs. “There is no way to change this in the near term,” he said.
- ▶ A regulator at the CFDA commented that the CFDA has just been merged into a new super regulator, the National Supervisory Commission. Under the commission, the newly appointed head of the medical insurance administration, Hu Jinglin, comes not from the health or pharmaceutical world but from the Ministry of Finance. “This means that the first responsibility of the health administration is to protect the integrity of the Health Insurance Fund, which is to say that the regulators will not look just at whether a drug is effective but whether the insurance system can accept its costs.”

The experience of foreign companies that have gotten their international blockbuster drugs into the China market supports this gloomy outlook. Abraxis announced approval in China of Abraxane, now a Celgene drug, in 2009 and sales were \$48 mln in 2015, according to IMS. In 2016, according to BeiGene, Revlimid and Abraxane sales in China were \$65 mln, so sales growth has been behind GDP growth. In Q1 2018, BeiGene reported that sales of Abraxane, Revlimid, and Vidaza together amounted to \$23.5 mln or \$94 mln on an annualized basis. Altogether, these sales are insignificant as a portion of international sales.

The Bayer/Onyx Pharmaceuticals drug Sorafenib, marketed as Nexavar as a treatment for kidney, liver, and thyroid cancer, was approved in 2000 in the U.S., and



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was widely expected to be a multi-billion dollar drug in China, where liver cancer is 19% of cancer-related deaths. But the drug has been a disappointment. Approved in 2008, Nexavar has never gotten onto the national reimbursement list in China. Bayer reported declining sales for Nexavar in 2015-17 throughout the world but especially in China and Japan.

**The drug candidates: Me too!**

Biochemists we spoke with call the BeiGene pipeline drugs “me too” drugs.

The two most anticipated pipeline drugs, the PD-1 and the PARP inhibitor, are well behind international competition in the development cycle and, if all goes perfectly, will enter a very crowded field. We identified five PD-1 inhibitors that are commercialized or close to approval.

**Table 2. Competing PD-1 Inhibitors**

	Bristol	Merck	Roche	Astra Zeneca	Pfizer
<b>Indication</b>	Opdivo (Nivolumab)	Keytruda (Pembrolizumab)	Tencentriq (Atezolizumab)	Imfinzi (Durvalumab)	Bavencio (Avelumab)
<b>2L+ Urothelial</b>	Approved	Approved	Approved	Approved	Approved
<b>2L NSCLC</b>	Approved	Approved	Approved	Approved	Phase 3
<b>R/R Hodgkin's</b>	Approved	Approved	Phase 2	Phase 2	n/a
<b>1L HCC</b>	Approved	Phase 3	Phase 3	Phase 3	n/a
<b>2L Esophageal</b>	Phase 3	Phase 3	n/a	Phase 2	Phase 3

Source: Company reports

On July 26, Merck [announced](#) that its Keytruda PD-1 therapy for melanoma was approved in China. This was the first approval for a PD-1 therapy for melanoma in China and represents a significant setback for BeiGene.

About the PARP inhibitor, a biochemist familiar with these drugs commented: “There are several of them out there, and they’ve under-performed in every respect.” Tesaro (TSRO) “also has a PD-1 and is farther along [than BeiGene]” he said.

As for BeiGene’s near-term candidate, Zanubrutinib, that drug would have to restart trials in the U.S. to gain access to that market. In China, we believe it has a chance of only modest sales. The drug most similar to Zanubrutinib is AbbVie’s Ibrutinib, marketed as Imbruvica and sold in China by Janssen. Given approval only in 2017, it is too early to have sales numbers on Imbruvica. But the drug, which costs ¥48,600 for a one-month supply, has been approved for insurance reimbursement

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in just one province, Zhejiang. In that province, according to our interviews, the individual must pay ¥20,000 annually for the drug and, after that minimum has been reached, the provincial insurance pays 60% of the cost, but after a 60% subsidy from the manufacturer. Meanwhile, the Bangladeshi company Beacon Pharmaceuticals Ltd., was approved last August to sell Ibrutix, an Ibrutinib drug that is advertised for exactly the same indications, which costs less than 25% of the price of Ibrutinib. Beacon, which is listed on the Bangladeshi exchange, does not offer a breakdown of revenue by product or region, but, based on public comments in news articles, regulators are positively disposed toward Ibrutix as an alternative to other forms of Ibrutinib.

Photo from the Hebei Province Health Bureau website September 20, 2017 <http://zmd.yywsb.com/article/201709/1219447.html>

### Celgene relationship

Perhaps the most compelling evidence that BeiGene will have trouble selling in high volume in China is the fact that its partner Celgene divested its commercial operations in China to BeiGene last summer. Celgene sold the operation to BeiGene for \$28.1 mln, of which just \$4.5 mln was in cash. The sale conveys to BeiGene the commercialization rights for Celgene drugs Revlimid, Abraxane, and Vidaza, all big drugs for Celgene. Revlimid made up nearly 70% of Celgene’s total revenue in 2017, bringing in \$8.2 bln, and Abraxane brought in \$992 mln. Yet the two drugs earned \$65 mln in China in 2017, based on BeiGene and Celgene statements, even

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though they have been in the market for several years. No wonder Celgene wanted to offload its China operation.

The deal with Celgene also gave BeiGene a \$211 mln windfall in licensing revenue, when Celgene took over commercialization ex-Asia of BeiGene's programmed cell death protein-1 (PD-1) inhibitor, BGB-A317.

### The factories

BeiGene may know that its drug candidates are not likely to yield a big success, because the company is developing contract manufacturing facilities. BeiGene has an 11,000-square-meter facility in Suzhou for the manufacturer of small-scale molecules. To build this facility, the company borrowed ¥120 mln from the Suzhou Industrial Park in 2015. Additionally, BeiGene is building a 100,000-square meter biologics facility in Guangzhou, in partnership with the Guangzhou Development District and its affiliate, Guangzhou GET Technology Development Co., Ltd.

Biologics manufacturing is expensive and complex and much encouraged by the Chinese government. It requires a large reactor for fermentation to produce an antibody, which is then grown, separated, and purified. The facility must be highly sterile. Contract manufacturing is also low-margin and distracts from the business of research and development. If BeiGene had great confidence in its drugs, we believe, it would not divert attention and resources to manufacturing.

To fund this facility, Guangzhou GET lent BeiGene \$132.8 mln and made an equity contribution to the joint venture company of \$14.5 mln for a 5% share. That loan comes at 8% annual interest. Yet BeiGene had ample cash resources, \$837.5 mln in cash and short-term securities at the end of 2017. The company reported no interest income. Meanwhile, GET is a financial investors with no experience in pharmaceutical manufacturing or distribution. We question, then, why BeiGene borrowed money at 8% and is building this facility as a joint venture, when the company instead could have paid outright with idle cash and owned the company outright.

Moreover, BeiGene's facility will contribute to what is fast becoming a global glut of biologics facilities. "It's unusual for a company the size of Beigene to want to build its own facility," said the president of a contract manufacturing organization (CRO) active in China. "There is capacity out there that they could contract."

This executive, acquainted with BeiGene and its founder, said that there is too much capacity in biologics right now, and, in China, the capacity growth is the most rapid.

### Executive sales

BeiGene's co-founder, John V. Oyler, has been selling shares regularly since the

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company listed in 2016 and has made \$122 mln for himself in two years. That does not suggest strong confidence in the company's ability to live up to and expand its valuation.

**Table 3. Oyler's Share Sales**

Max Trade Date	Type	Shares	Price	Value
6/26/2018	Award/Acquisition	188,266	-	-
4/30/2018	Award/Acquisition	574,938	-	-
3/2/2018	Sale -PlannedP	99,000	\$145.63	\$14,416,931
2/28/2018	144 Sale -PlannedP	99,000	\$150.96	\$14,945,040
2/13/2018	Ben. Ownership (13D/G)	-	-	-
12/26/2017	Sale -PlannedP	20,137	\$96.46	\$1,942,515
12/8/2017	Sale -PlannedP	380,863	\$86.53	\$32,954,565
9/27/2017	Award/Acquisition	515,000	-	-
7/6/2017	Sale -PlannedP	317,900	\$58.42	\$18,570,746
6/22/2017	144 Sale -PlannedP	317,900	\$44.58	\$14,171,982
5/1/2017	Sale -PlannedP	36,149	\$40.47	\$1,462,808
3/20/2017	Sale -PlannedP	15,951	\$40.02	\$638,348
3/16/2017	Sale -PlannedP	190,000	\$40.61	\$7,715,065
2/16/2017	144 Sale -PlannedP	387,440	\$40.43	\$15,664,199
2/13/2017	Ben. Ownership (13D/G)	-	-	-
2/8/2016	Conversion -Acq	9,398,380	-	-
<b>Total sold 2016- June 2018</b>				<b>\$122,482,199</b>

Source: Company financials, J Capital Research

Co-founder and scientific lead Wang Xiaodong has sold around \$23 mln in shares.

Despite the complete lack of proven results, BeiGene offers very high share compensation to its employees. "As of December 31, 2017," reads the 2017 10-K, "there was \$178.2 million of total unrecognized share-based compensation expense, net of estimated forfeitures, related to unvested share-based awards which are expected to be recognized over a weighted-average period of 3.4 years." That number was up by more than \$100mln over 2016.. (2017 10-K p 114)

### Company history

BeiGene's co-founder is John V. Oyler, a China-based McKinsey graduate who had

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tried his hand at starting a China-based Contract Research Organization (CRO), BioDuro, before BeiGene. BioDuro was sold to Pharmaceutical Product Development. Oyler is generally well regarded though thought to be weak in business management.

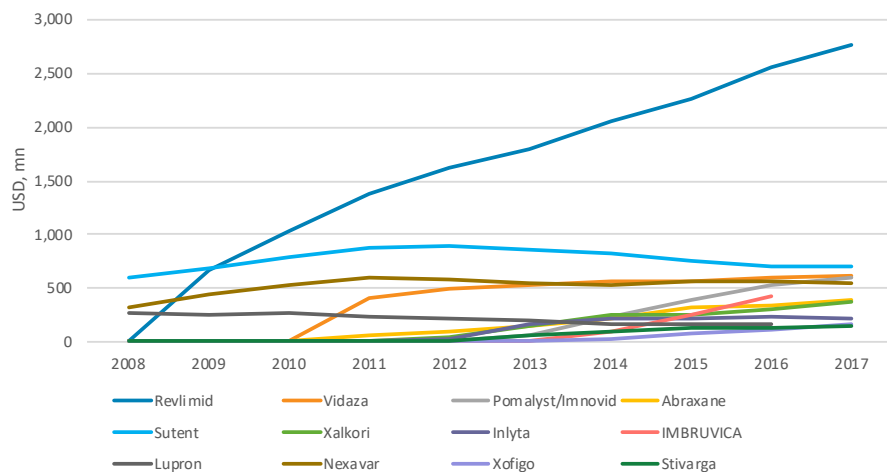
The co-founder is Dr. Wang Xiaodong. Wang is a well-regarded research scientist formerly at the University of Texas Southwestern Medical Center in Dallas. In 2003, still based in Texas, Wang established the National Institute of Biological Science in Beijing. In 2010, he came to China to work full time.

In April this year, BeiGene added Dr. Wu Xiaobin as the general manager of the China operation. Wu was former country manager for Pfizer China and manages the commercial side of the operation.

BeiGene's communications are promotional and invite skepticism. On July 24, just after announcing it had filed to list in Hong Kong, BeiGene filed an 8-K guiding to \$125 mln annual sales in China in 2018, double the run rate of Q4 2017. The company does not explain why product sales would double in two quarters, when the Celgene team in Shanghai had been laboring to sell the same three drugs for years.

Apart from Revlimid, international sales of cancer drugs have not grown particularly fast. In our channel checks, we have been unable to identify a surge in China sales for Revlimid. In fact, we spoke with pharmaceutical company reps who sell within Chinese hospitals. They said they believed that Revlimid sales were flattish, because, even though the drug was admitted to the national insurance list, it is not now being reimbursed, because regulators are in talks with the company to reduce the price.

**Chart 1. International Sales Growth of Blockbuster Cancer Drugs**



Source: Company reports

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BeiGene has been a serial raiser of cash. The company has raised over \$1 bln in financing since 2014. On July 24, BeiGene filed for a dual listing in Hong Kong and will raise more. We expect the listing in Hong Kong to be followed by listings for other Chinese biotech plays, of which there are many. We do not think that BeiGene deserves the lofty valuation ascribed to it.

### Valuation

We value BeiGene on a DCF basis with the following assumptions:

- ▶ Zanutbrutinib commercialization and inclusion in the national drug reimbursement list in 2020
- ▶ Commercialization of the PD-1 inhibitor in 2020
- ▶ Celgene drug sales growth of 14% annually
- ▶ Constant collaboration revenue from partners other than Celgene
- ▶ 15% royalties on commercialization of the PD-1 inhibitor ex-China
- ▶ A terminal growth rate of 2.5%
- ▶ A WACC of 8.5%

On that basis, our valuation is \$71.60, 59% lower than the current share price.

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