EDISON

Casi Pharmaceuticals

Initiation of coverage

Riding the wave of Chinese reform

Pharma & biotech

We are initiating coverage on CASI Pharmaceuticals, which is focused on leveraging regulatory synergies between the US and China to quickly bring products to market. The regulatory environment in China is rapidly evolving and is actively encouraging the entry of foreign drugs. CASI intends to leverage this with a portfolio of three proprietary oncology drugs (licensed from Spectrum) and 30 ANDAs (bought from Sandoz and Laurus Labs). We arrive at an initial valuation of $754m or $8.06 per share.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.0	(6.5)	(0.12)	0.0	N/A	N/A
12/17	0.0	(10.1)	(0.16)	0.0	N/A	N/A
12/18e	0.0	(18.8)	(0.23)	0.0	N/A	N/A
12/19e	9.6	(15.1)	(0.16)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Rapidly changing landscape in China

The Chinese regulatory authorities have made a series of substantial changes to their process for drug approval in recent years to improve the availability of new drugs. The Chinese FDA (CFDA) has established new classes of applications for drugs that are previously approved outside of China. Additionally, there is a set of criteria for priority review, which can significantly reduce review times.

Proprietary portfolio from Spectrum Pharmaceuticals

CASI was granted greater Chinese rights to Evomela, Marqibo and Zevalin in 2014 for 17% of CASI stock and a $1.5m note. All three drugs are indicated for hematologic malignancies that are approved in the US ($53.6m combined sales). The company intends to seek approval through the novel import drug pathway in China, which would require only a small Phase III study, although regulators recently indicated they would accept foreign data. Evomela (which would be the first formulation of melphalan in China) is poised to test this following its recent selection for priority review. Feedback from a recent AdCom is anticipated in Q318.

Total of 30 generics for both markets

CASI has acquired 30 ANDAs from Sandoz and Laurus Labs. The goal with the portfolio is to transition manufacturing of the drugs to China, which should ensure priority review in China. The company can then manufacture for both the China and US markets at reduced cost. The highest impact drug is entecavir for hepatitis B, which has 30m chronic infections in China and a $1.5bn market.

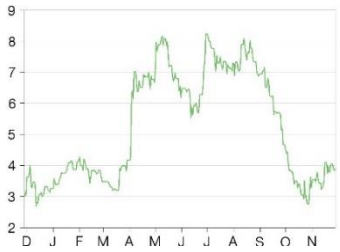
Valuation: Initiated at $754m or $8.06 per basic share

We arrive at an initial valuation of $754m or $8.06 per basic share. This is driven by the generics with a value of $578m, based on a peak sales estimate of $250m, roughly split between the US and China. This is based on 4% and 2% average market share in the respective countries. We do not expect the company to require additional financing before profitability in 2021.

29 November 2018

Price	**US$3.9**
Market cap	**US$365m**
Net cash ($m) at Q318	98.5
Shares in issue	93.6m
Free float	46%
Code	CASI
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	40.8	(44.1)	23.8
Rel (local)	36.4	(41.0)	18.5
52-week high/low	US$8.23	US$2.68	

Business description

CASI is a pharmaceutical company that has acquired or licensed a series of drugs that it intends to market in China. These include proprietary drugs licensed from Spectrum Pharmaceuticals and a portfolio of ANDAs. The goal is to seek approval through new pathways that have been opened in the quickly changing Chinese regulatory environment.

Next events

Evomela priority review decision	Upcoming
Marqibo and Zevalin CTAs	Upcoming

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Investment summary

Company description: Leveraging change in China

CASI is a NASDAQ-listed, US-based pharmaceutical company focused on acquiring or licensing products approved in the US and bringing these drugs to the Chinese market. CASI is leveraging recent regulatory reforms in China that have provided speedier routes to market for drugs that are already approved in other geographies. It previously in-licensed the rights in greater China for a series of drugs from Spectrum Pharmaceuticals (Evomela, Marqibo and Zevalin) and is seeking Chinese approval for these medicines, potentially using data from the US approval package. CASI has also bought a series of 30 abbreviated new drug applications (ANDAs) and plans to transfer manufacturing of some of these drugs to China to supply the Chinese and US markets.

Valuation: Initiated at $754m or $8.06 per basic share

We arrive at an initial valuation of $754m or $8.06 per basic share. We value the drugs licensed from Spectrum collectively at $75.7m, based on a risk-adjusted NPV analysis and $47.6m combined peak sales. We expect Evomela to be the first of these approved as it is the first formulation of melphalan to enter China and has been through an advisory committee. Our valuation of the generics portfolio is $578m, based on a peak sales estimate of $250m, roughly split between the US and China, with margins in line with other low-cost manufacturers (58%), but low market shares (4% and 2% average for individual indications in US and China respectively).

Financials: $98.5m net cash likely all that will be needed

CASI reported a net loss of $8.8m for Q318, and we expect a loss of $26.0m in 2018 compared to a loss of $10.8m for 2017. This increase is driven by increasing operational costs associated with the regulatory and commercial operations in China. The company will likely license manufacturing in China while it builds out its internal capacity, and will require a salesforce and operational overhead associated with bringing the drugs to market. This is offset by lower R&D costs following the completion of Chinese registration trials. CASI ended Q318 with $100m in gross cash, following the first $37.5m tranche of its September private placement (in total $48.5m: 9.0m shares at $5.36 and 2.7m warrants at $7.19). We expect net cash of $98.5m to provide a runway to profitability in 2021.

Sensitivities: Unique to the trans-Pacific strategy

The risks that CASI faces are unlike many other pre-commercial pharmaceutical companies and are contingent on the company executing on its strategy to leverage recent Chinese regulatory reform to its benefit. Clinical risk is substantially limited as all its products have been vetted by approval in the US. There is uncertainty in China given the pace of reform and there is little or no precedent for certain pathways to market. For instance, the government signaled it would accept foreign clinical data in late 2017, but the scope of this provision and how it will be implemented in policy is unknown. Moreover, the State Council has signaled it intends to substantially reform the generics market in China and although we expect these reforms to favor CASI, we cannot be certain of the outcome. The company also faces significant commercial risks across its portfolios. The drugs licensed from Spectrum had limited traction in the US and the level of Chinese market demand is unknown. Evomela should be the first approval for a product containing melphalan in China, which may offset some of this risk. We expect the generics portfolio to face substantial competition, because China has a highly fragmented generics market with as many as 5,000 generics companies served by 13,500 distributers. Other factors such as financing risk are limited given the quick pathway to market for these drugs.

Testing the waters in a new Chinese healthcare market

CASI is a pharmaceutical company based in Rockville, Maryland, utilizing newly opened regulatory pathways to develop drugs in China to support the delivery of these drugs to this market, as well as the US and the rest of the world. The company was formerly EntreMed, but changed its name in 2014 following the shift in its strategy away from internal development (although it retains the same management). The company's near-term commercial focus is on the in-licensing of drugs that are approved in other geographies, and performing the requisite regulatory filings and clinical studies to receive approval in China. This allows it to leverage recent regulatory reforms in China that allow for expedited pathways to market for drugs with foreign approvals. CASI's product pipeline features three US FDA-approved drugs in-licensed from Spectrum Pharmaceuticals for China regional rights. Two are moving through this process and are under review, while one, Evomela, is going through a new priority review process with the CFDA.

There are additional opportunities for the company to use the new Chinese regulatory framework for generic medications. Similarly, holders of US-approved ANDAs have lower regulatory requirements to bring generic medications to China. CASI's plan is to transition manufacturing to China and simultaneously seek generic drug approval in China and an amended ANDA (for new manufacturing) in the US, allowing it to leverage low-cost Chinese production capacity in both markets. The company has acquired 29 ANDAs (25 approved and four pending) from Sandoz, and an additional ANDA for tenofovir disoproxil fumarate from Laurus Labs.

Finally, outside of the company's in-licensing and regulatory business strategy, it has several development-stage assets. It is developing ENMD-2076, a small molecule kinase inhibitor, in Phase II for fibrolamellar carcinoma, previously developed by EntreMed. Additionally, the company has two preclinical immunoncology drugs CASI-001 and CASI-002 (although little is known about these programs and they are not included in this report).

Exhibit 1: CASI drug portfolios

Portfolio	Drug	Indication	Notes
Chinese rights licensed from Spectrum			
	Zevalin (ibritumomab tiuxetan)	Non-Hodgkin's lymphoma	CTA under review
	Marqibo (vincristine sulphate liposome)	Acute lymphoblastic leukemia	CTA under review
	Evomela (melphalan)	Multiple myeloma	No melphalan approved in China, received priority review from CFDA
ANDA portfolio (selection)			
	Entecavir	Hepatitis B	$800 per patient reimbursement in China, 20m chronic hepatitis B virus infections in China
	Tenofovir disoproxil fumarate	Hepatitis B, HIV	
	Repaglinide	Diabetes	
	Bisoprolol fumarate	Hypertension	
	Cilostazol	Peripheral vascular disease	
	Methimazole	Hyperthyroidism	
	Tizanidine	Muscle relaxant	
Development stage drugs			
	ENMD-2076	Fibrolamellar carcinoma, triple negative breast cancer	Phase II ongoing
	CASI-001	Immunoncology	Preclinical
	CASI-002	Immunoncology	Preclinical

Source: CASI. Note: CTA=clinical trial authorization.

The Chinese market

China is the largest pharmaceutical market in the world by volume with a population of 1.4 billion, but attempts to penetrate its pharmaceutical market have historically been limited. In 2015 the total

US drug exports to China were only $2bn.[1] However, the situation is rapidly changing with the adoption of new policies across all healthcare market segments to promote improved care, greater innovation and international collaboration. These include initiatives to improve the quality of pharmaceutical products and reduce regulatory bottlenecks.

Reimbursement in China

China's reimbursement system is almost entirely public, with 97% of individuals covered. Chinese citizens are covered under one of three schemes: Urban Employee Basic Medical Insurance (UEBMI), Urban Resident Basic Medical Insurance (URBMI), or New Rural Cooperative Medical Scheme (NRCMS). To complicate matters further, each of these schemes varies based on local government, with wide variations in benefits. UEBMI is by far the best-funded program and the predominant payer in terms of volume, despite only covering 19% of the population. Reimbursement is 75% for inpatient procedures and drugs, and outpatient costs are typically handled via a medical savings account (MSA), which is mandatory for payees and is financed primarily by payroll taxes.

Exhibit 2: Chinese insurance schemes

Program	Acronym	Fraction of population	Target pop.	Inpatient/outpatient reimbursement	Coverage ceiling
Urban Employee Basic Medical Insurance	UEBMI	19%	Urban employees	55%/50%	6x average local worker's wage
Urban Resident Basic Medical Insurance	URBMI	16%	Urban children, unemployed, disabled	75%/use of MSA*	6x average local disposable income
New Rural Cooperative Medical Scheme	NRCMS	62%	Rural residents	55%/50%	8x average local farmer's income

Source: Yu,[2] Hu and Mossialos.[3] Note: *MSA = medical savings account.

Despite the high number of insured individuals, there are still significant hurdles to receiving care in China. Generally, patients pay for medical procedures upfront then apply for reimbursement, which puts patients with low amounts of disposable income at a significant disadvantage. Additionally, although the NRCMS has had significant success in extending coverage to vulnerable people in China's countryside, this population continues to have issues with access to quality care.

Historically, deficiencies in the public health insurance infrastructure have been met through out-of-pocket spending. The total out-of-pocket contribution for healthcare costs was 33% in 2011 and the government has stated a goal of reducing this to 30% by 2018.[2] These expenses have been implicated in the exceptionally high rate of household saving in China at 38% in 2014, the highest in the world.[4] This savings rate has consistently increased since the early 2000s with the ageing population of China. In a given year, approximately 13% of Chinese households experience a catastrophic medical expense, defined as spending of more than 40% of their disposable income,[5] so the need to address significant out-of-pocket medical costs is a common occurrence.

There are several national regulatory schemes in China that determine drug pricing and reimbursement, although they only cover a portion of the drugs that are commercially available in China. The Essential Drug List (EDL) names widely used, low-cost generics that are intended as drugs required for basic care. The National Reimbursement Drug List (NRDL) is a separately administered list of drugs, divided into two parts: Class A for essential generics, which heavily overlaps with the EDL, and Class B, which includes more expensive and non-generic drugs. In

1 International Trade Administration

2 Yu H (2015) Universal health insurance coverage for 1.3 billion people: What accounts for China's success? *Health Pol.* 119, 1145-1152.

3 Hu J and Mossialos E (2016) Pharmaceutical pricing and reimbursement in China: When the whole is less than the sum of its parts. *Health Pol.* 120, 519-534.

4 Organisation for Economic Co-operation and Development

5 Ouyang Y (2013) China tackles illness-led poverty as financing gap grows. *Lancet Onco.* 14, 19.

theory, drugs on the EDL and NRDL Class A are fully reimbursed, although in practice this is limited by the resources of the individual insurance schemes and local jurisdiction. The NRDL Class B list is reimbursed on a provincial level with copays of between 10% and 90%. The prices of these drugs also have a high degree of variability compared to their western counterparts, ranging from 30% or less of the US list price for innovative cancer drugs to par for low-cost generics and subsidized programs. A limitation of the NRDL historically has been the frequency at which it was updated: the list received its first revision in eight years in early 2017. The government is also developing the so-called major disease schemes system, which provides reimbursement at a minimum of 50% for patients with certain high-cost conditions such as cancer or autoimmune disorders. These programs are still in the pilot stages.

Exhibit 3: Chinese drug reimbursement schemes

Program	Reimbursement	Notes
Essential Drug List	100%	Basic, low-cost generics
National Reimbursement Drug List: Class A	100%	Overlaps with EDL
National Reimbursement Drug List: Class B	10-90% copay provincially determined	Higher priced, innovative drugs
Major disease schemes	Minimum 50%	In development

Source: Various

Recent regulatory changes

One of the biggest focuses of regulatory reform in the Chinese healthcare system has been improving the availability of innovative medicines. A major limiting factor in the approval of new drugs in China has been regulatory backlog. Historically, a new drug application was filed each time a manufacturer launched a competing generic and there was no apparatus to effectively identify which applications should receive priority review. As of 2014 there were approximately 19,000 open drug applications, and fewer than 100 employees involved in their review at the CFDA. In efforts to reduce the backlog, the agency has increased the number of reviewers to 600 and reduced the number of outstanding applications to approximately 4,000 by the end of 2017.[6]

The agency has also instituted a series of pathways to market to expedite the approval of innovative drugs. In particular, these new policies open up the process to drugs that have been approved by foreign regulatory agencies. In June 2017, the CFDA joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the organization tasked with standardizing drug approval standards across regulatory agencies. To facilitate the approval of foreign medicines and align its process with foreign agencies, the CFDA created a series of new drug classifications, which take into consideration the approval status of a drug overseas and reduce the clinical requirements for drugs that have been approved elsewhere (Exhibit 5). However, in October 2018, the State Council announced a draft proposal that would further reduce the clinical burden for imported drugs by allowing the CFDA to accept overseas clinical trial data as part of Chinese application packages. The proposal included the requirement that application include clinical data on 'the existence of ethnic differences,' presumably to ensure similar activity in Chinese populations. This requirement is in accordance with the historical motivation for requiring additional Chinese clinical trials. The degree of implementation of this policy or the precise requirements for foreign data are unclear, as the draft proposal did not include specifics or a timeline for implementation. The extent to which these policies will differ between innovative drugs and generics is also unclear. However, CASI is aggressively pursuing the approval of its drugs in accordance with the new guidance and has submitted an NDA application for Evomela without conducting Chinese clinical trials (more information below). Additional reforms to encourage the import of medicines were announced at the meeting of the State Council in April, including the removal of import tariffs and reduced VAT on "common drugs" including all anticancer drugs.

[6] CFDA 2017 Drug Review Report

Exhibit 4: New drug classifications

Class	Definition	Regulatory status	Local clinical development	Application process
1	New drug	Not marketed globally	Phase I, II, III	New drug
2	Modified or improved drug	Not marketed globally	Phase I, II, III	New drug
3	China-manufactured generic	Approved outside of China	PK and Phase III	Generic drug
4	China-manufactured generic	Approved in China	BE	Generic drug
5.1	Imported innovative drug	Approved outside of China	PK and Phase III	Import drug
5.2	Imported generic drug	Approved outside of China	BE	Import drug

Source: Wang et al.[7] Note: PK=pharmacokinetics, BE=bioequivalence.

The agency has set up a series of criteria for priority review to shorten the time to approval for new drugs. According to the agency's most recent report on the program, it takes approximately 39 days to process a priority CTA, 59 days for an NDA and 81 days for ANDA. Priority review is awarded to:

- Innovative drugs not approved elsewhere
- Innovative drugs that will be manufactured in China
- Innovative drugs for HIV, hepatitis, rare diseases, malignant tumors and pediatric diseases, among others
- Newly launched generics

China is also reforming its approach to intellectual property with regard to pharmaceuticals. It is moving to a patent-linkage system similar to that present in the US, where a generic applicant must reference the originator patent and inform the holder, thus initiating an appeals process. The CFDA also proposed a series of data exclusivity periods for different classes of drug: six years for an innovative small molecule and 12 for a biologic. We expect this data exclusivity to be the primary method by which CASI protects the drugs in the Spectrum portfolio.

Finally, regarding regulatory reforms, the Chinese government announced in March 2018 that the CFDA, as well as other healthcare agencies, would be reorganized into a larger market regulatory body. We expect this reorganization to increase governmental pressure on the agency, but that most of the CFDA's previous mandate will remain intact.

Spectrum portfolio

In September 2014, CASI was granted the Chinese rights (including Taiwan, Hong Kong and Macau) to three drugs, Zevalin, Marqibo and Evomela, from Spectrum Pharmaceuticals in exchange for approximately 17% of CASI stock and a $1.5m promissory note. The agreement does not include any milestones or royalties to Spectrum, but CASI is obligated to pay the China portion of royalties and milestones owed to Spectrum's upstream licensees. CASI may have to perform a Phase III clinical trial for each medication to receive approval. In general, these products are modified versions of other approved medications: novel formulations in the case of Evomela and Marqibo, and a radio-labeled derivative in the case of Zevalin. The patent terms for these products are limited (estimated at 2029, 2020 and 2019 for the three products, respectively), but additional protection may be provided in China via data exclusivity. In accordance with the most recent guidance, Evomela and Marqibo should be eligible for data protection of six years as innovative drugs, whereas Zevalin should be eligible for 12 years as a biologic.

[7] Wang B, et al. (2017) An overview of major reforms in China's regulatory environment. *Reg Rapporteur* 14(7/8), 5-9.

Evomela

Evomela is a proprietary formulation of melphalan, a nitrogen mustard chemotherapy agent. Melphalan has a low solubility in water and the generic drug is commonly prepared with propylene glycol as an excipient to improve solubility, although this is associated with certain toxicities such as lactic acidosis, renal dysfunction and hemolysis. Evomela instead uses the proprietary cyclodextrin Captisol (developed by Ligand Pharmaceuticals) as a solubilization agent to avoid these effects and provides the additional benefit of increased stability after preparation. A 20% royalty on sales is owed to Ligand for the product.

Evomela is approved in the US for use as a conditioning agent before undergoing hematopoetic stem cell transplantation in patients with multiple myeloma. The drug is essentially used to kill the body's malignant bone marrow before it is replaced in the transplant. In the 61-person, open-label, single-arm pivotal trial, the drug combined with stem cell transplant improved response rates (partial response or better) from 79% to 95% following transplant. The safety profile was consistent with high-dose melphalan, with any toxicities typically associated with propylene glycol. The drug is also approved for the minor indication of patients with multiple myeloma who cannot take oral medications. The drug was launched in 2016 and Spectrum reported sales of $35.2m in 2017. We estimate pricing of around $14,000 for a conditioning regimen in the US.

As with other hematologic malignancies, multiple myeloma is significantly rarer in China than in the west. The age-adjusted incidence rate is 0.8 per 100,000 person years,[8] compared to 3.3 in the US.[9] Currently there are no approved forms of melphalan in China. Because of this (and other factors such as multiple myeloma being a rare disease in China), the drug's CTA was granted priority review in September 2017.

The company subsequently announced on 5 April 2018 that it has also submitted an NDA application, which was accepted for priority review under the CFDA's new guidelines. The application was reviewed by an advisory committee (25-26 April 2018). This application was presumably made on the basis of the new draft policy on the acceptance of foreign clinical trial data. It is unclear if the clinical trial data will satisfy the clause on the 'the existence of ethnic differences': the registration study for Evomela (a 61-patient Phase IIb study) only included a single Asian participant (reported as 2% of enrolment). However, there is little precedent to draw any conclusion from and this will be an interesting test of the implementation of the new policy. The company did report that it had received a standard set of questions back from the agency, which typically reflect the final stage of the Import Drug review process.

Marqibo

Marqibo is a liposomal formulation of vincristine, a chemotherapy used in the treatment of hematologic and solid tumors. The goal of the development of the liposomal formulation was to improve the pharmacokinetic profile of the drug by increasing circulation time and reducing off-target tissue exposure. The drug is approved in the US for Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) in the third line. The drug was approved with an open-label, single-arm registration trial of 65 relapsed and refractory patients. Three patients had a complete response (CR, 4.6%) and an additional seven patients had a complete response with incomplete blood cell recovery (CRi, 10.8%). Marqibo was launched in 2013 and sold $6.6m in 2017, with an estimated list price of $112,000 per course.

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8 Globocan

9 SEER

10 Chen W, et al. (2016) Cancer statistics in China, 2015. *CA: Can. J. Clin.* 66, 115-132.

The estimated incidence of all forms of leukemia in China is approximately 5.5 per 100,000 person years.[10] Based on statistics from western countries, we estimate the rate of adult ALL in China at 1.0 per 100,000, 80% of which are expected to be Ph-.[11] The drug is under technical review at the CFDA for its CTA.

Zevalin

Zevalin is an antibody targeting CD20 with an yttrium-90 radio-label. CD20 is the same protein on B-cells that is target by the blockbuster Rituxan (rituximab). Zevalin is used in combination strategy with Rituxan for the treatment of follicular non-Hodgkin lymphoma (NHL) in the second and higher lines and for consolidation in the first line. The therapy is designed to improve standard anti-CD20 therapy by providing a dose of radiation to accumulations of B-cells in the lymph nodes. The drug was shown to improve progression-free survival compared to Rituxan alone, albeit at the risk of inducing radiation-associated malignancies such as myelodysplastic syndrome. In the pivotal study (open-label, randomized), the Zevalin arm had a complete response rate of 38% vs 18% for Rituxan alone. The drug has been on the market since 2002 and Spectrum sold $11.8m of it in 2017. We estimate that Zevalin costs approximately $66,000 per treatment.

Based on the underlying rate of 6.4 per 100,000 cases of non-Hodgkin's lymphoma in China,[10] we estimate a rate of follicular lymphoma of approximately 1.3.[12] Zevalin is also under technical review for its CTA.

The generics portfolio

On 26 January 2018, the company announced it had acquired a portfolio of 25 approved and four pending ANDAs from Sandoz for $18m (Exhibit 5). Most of these drugs are already included on the NRDL in one form or another, and CASI intends to select certain products from the list that it believes have significant market potential in the US and China. Based on IMS data provided by CASI, the top eight key US products (midodrine, triamterene/HCTZ, lisinopril, bisoprolol, cilostazol, diclofenac sodium and potassium, and nabumetone) had $62m in sales in 2016 under Sandoz (according to the company from IMS).

[11] Kurzrock R, et al. (1988) The Molecular Genetics of Philadelphia Chromosome–Positive Leukemias. 319, 990-998.

[12] American Cancer Society.

Exhibit 5: ANDAs from Sandoz

Drug	Indication	Chinese reimbursement list
Approved ANDAs		
Benazepril tablets	Hypertension	NRDL B
Bisoprolol fumarate tablets	Hypertension	NRDL A
Buprenorphine HCL sublingual tablets	Pain and addiction	NRDL B for patch
Cefprozil tablets	Antibiotic	NRDL B
Cilostazol tablets – 50mg	Peripheral vascular disease	NRDL B
Cilostazol tablets – 100mg	Peripheral vascular disease	NRDL B
Desvenlafaxine ER tablets	Depression	N/A
Diclofenac potassium 50mg tablets	Arthritis	NRDL A
Diclofenac sodium DR 25mg, 50mg tablets	Arthritis	NRDL A
Diclofenac sodium DR 75mg tablets	Arthritis	NRDL A
Econazole nitrate cream	Antifungal	NRDL B
Entecavir tablets	Hepatitis B	NRDL B
Epinastine HCl ophthalmic solution	Conjunctivitis	N/A
Heparin sodium for injection	Anticoagulant	NRDL A
Lisinopril tablets and Lisinopril BPP tablets	Hypertension	NRDL B
Methimazole tablets	Hyperthyroidism	NRDL A
Midodrine tablets	Hypotension	NRDL B
Nabumetone tablets	Arthritis	NRDL A
Naratriptan tablets	Migraine	N/A
Ondansetron HCL tablets	Nausea	NRDL A
Repaglinide tablets	Diabetes	NRDL B
Ribavirin capsules	Antiviral	NRDL A
Spironolactone tablets	Hypertension	NRDL A
Tizanidine tablets	Muscle relaxant	NRDL B
Triamterene/hydrochlorothiazide combination tablets	Hypertension	NRDL A in other formulations
Pending ANDAs		
Aripiprazole	Antipsychotic	NRDL A
Bepotastine ophthalmic solution	Antihistamine	N/A
Bromfenac ophthalmic solution	Anti-inflammatory	NRDL B
Telmisartan/hydrochlorothiazide	Hypertension	NRDL B

Source: CASI

We believe the company received an exceptionally good purchase price for the assets at $18m, and there are a number of factors contributing to this. First, these products represented a very small portion (likely 0.2% or less) of the overall revenue for Sandoz's parent Novartis (NVS) totaling $49.1bn in 2017, and this sale can be considered a disposal for strategic purposes. Also, a large number of the assets in the portfolio are widely used drugs that have been generics for a long time. The commoditized nature of these markets means that a large number of other companies already sell these products, and new entrants have limited market leverage in the US, both of which factors significantly reduce the number of potential buyers.

Additionally, the company announced in October 2018 that it had acquired an additional approved ANDA from Laurus Labs for the hepatitis B treatment tenofovir disoproxil fumarate (TDF) for $700,000 upfront and $2.3m in milestones.

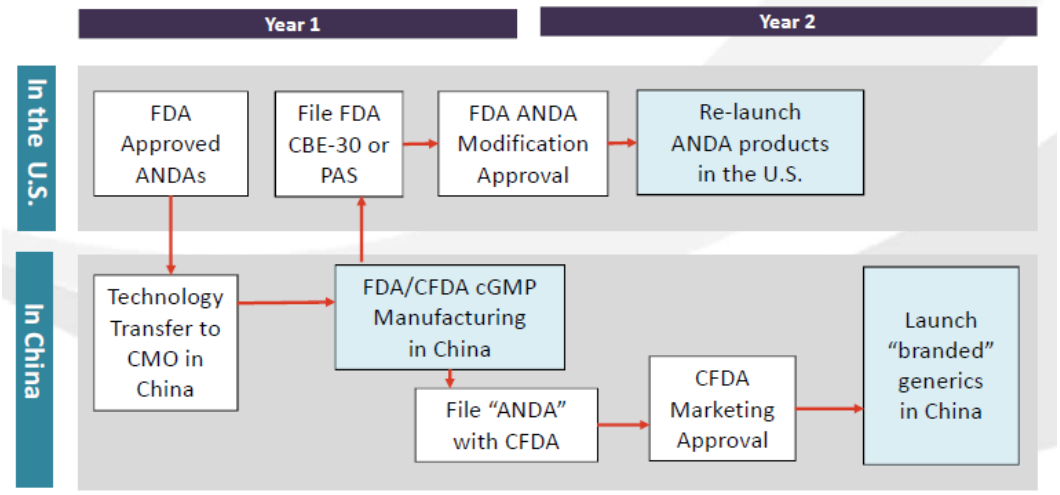
The value of these assets is significantly greater to CASI, which can utilize a combined China-US strategy. This strategy is two-fold (Exhibit 6):

- With access to the ANDAs, the company can use the data from these applications to support approval in China.
- The company can file ANDA amendments (CBE-30 or PAS) and move manufacturing to China to supply the US market.

Manufacturing in China provides two benefits. First, the company will be able to leverage the low cost of labor in China. This significantly increases the company's margins and provides increased leverage on price for the US market. This is a strategy that has been successfully employed by a number of generics manufacturers such as Sun Pharma and Dr Reddy's, which manufacture at low

cost in India. This has only recently become a viable option in China given the recent reforms and an increase in the number of facilities able to manufacture at US-FDA standards. This includes contract manufacturing organizations (CMOs), which the company intends to employ. Second, by manufacturing in China, the company will receive priority review for its ANDA applications to the CFDA. CASI will subsequently perform the bioequivalence studies needed for approval, allowing these products to rapidly enter the market. This is an avenue that was previously unavailable to generics companies such as Sandoz, and has the potential to dramatically increase the market for these products and the value of this portfolio.

Exhibit 6: CASI generics strategy



Source: CASI

The generic drug market in China

Despite the recent regulatory shift toward more branded and innovative pharmaceuticals, the drug market in China has been, and still is, dominated by generics. The market is highly competitive with as many as 5,000 generics companies, with the top 100 companies only comprising a third of total sales.[1] The situation is further complicated by a highly complex, multi-level distribution network of over 13,500 companies. This degree of competition and the low price point for medication in the country historically led to a problem with poorly manufactured, unsafe and counterfeit generics. However, this has been met with a severe government crackdown after a public outcry. With the increasing focus on adopting international manufacturing standards, the review process for generics has shifted from a focus on manufacturing to market authorization holders. Previously, only drug manufacturers could seek approval for generics whereas now manufacturing can be outsourced. We expect the company to outsource its manufacturing in the short term to support the initial supply needs. However, it has stated that it intends to break ground on its own production facility in the Wuxi Huishan Economic Development Zone in 2019. We expect this to support its long-term production needs as the company scales.

In April 2018, the State Council released a policy opinion regarding generic drugs. It outlined new potential policy on three fronts: the promotion of generic development, improvement in drug quality and post-approval support. These policies are generally in line with advancing the agenda of increased oversight and speedier approval pathways. However, the council also signaled to increasing support from insurance programs, with promises to "promptly include eligible drugs into in the catalogue." In general, these measures described in the opinion, if implemented, will be supportive of CASI's business model, by both increasing oversight and encouraging new drug entry and reimbursement. However, given the fragmented nature of the market, we expect small market

shares (2% on average) for any given drug. In addition, we expect overhead costs in excess of 10% to facilitate securing distribution.

Exhibit 7: Selection of Chinese drug sales

Drug	Total 2016 Chinese sales ($m)
Entecavir	1,490
Repaglinide	225
Bisoprolol fumarate	205
Cilostazol	65
Methimazole	29
Tizanidine	21

Source: PDB Database via CASI

Entecavir and TDF

A noteworthy drug from the Sandoz portfolio is entecavir, which is an antiviral used in the treatment of hepatitis B virus (HBV). Entecavir plays a prominent role in these treatment efforts. It is an antiviral therapy that effectively suppresses viral load, but does not cure the disease. A recent study on pricing estimated the cost per year in China to be $1,000 to $1,400, varying by province ($1,258 on average).[13] Total sales in China for 2016 were $1.5bn.[14] Reimbursement for the drug also varies by region, but has been reported in the 75-85% range in cities.[15] Due to these factors, the market potential for entecavir is the highest of the drugs in the portfolio. Because of this, there are a number of well-established competitors in China, including the drug originator Bristol-Myers Squib with branded Baraclude.

The recent acquisition of the ANDA for TDF from Laurus Labs follows a similar strategy. TDF is an antiviral that is indicated for the treatment of HIV and HBV. It occupies a similar market segment to entecavir and is used in the first line. The drug has previously been a target of drug pricing controversy in China. The product was marketed in China by Gilead (under its brand name Viread), which made dramatic price cuts to the drug to appease regulators but, unsatisfied, the Chinese government revoked the patents on the drug in 2013, effectively making it generic. The drug was subsequently marketed in China for HBV by GSK, which in 2016 again dropped the price to approximately $70 a month.

China has historically had the largest worldwide burden of HBV. In a 2002 study, 120 million people were found to be carriers of the disease and an estimated 30 million individuals had chronic infection.[16] However, there have been systematic efforts to address the issue both through immunization and post-exposure treatment. Despite these efforts, the World Health Organization reports that there are approximately 90 million carriers of the disease in China.

ENMD-2076

CASI has a single ongoing clinical development program for ENMD-2076, a multi-tyrosine kinase inhibitor (TKI) in Phase II. The drug is being studied for the treatment of fibrolamellar carcinoma and triple-negative breast cancer (TNBC) in both China and the US. The drug inhibits three classes of TKs: Aurora kinases (Aurora A), angiogenic receptors (VEGFR, FGFR) and growth factor receptors (FLT-3, c-KIT, CSF1R). Each of these classes has previously been targeted in the clinic by other

[13] Hill A, et al. (2015) Analysis of minimum target prices for production of entecavir to treat hepatitis B in high- and low-income countries. *J Vir Erad* 1, 103-110.

[14] PDB Database via CASI.

[15] Qiu Q, et al. (2014) Impact of a new reimbursement program on hepatitis B antiviral medication cost and utilization in Beijing, China. *PLoS One* 9, e109652.

[16] Jiu J and Fan DM (2007) Hepatitis B in China. *Lancet* 369, 1582-1583.

companies. Aurora A is a regulator of the cell cycle that promotes cancer growth and is a known oncogene. This family has been a target in a large number of ongoing and discontinued clinical studies in both solid and hematologic cancers, although none have been approved. The remainder of the inhibition profile for both angiogenic and growth factor receptors is similar to other multi-TKIs such as Nexavar (sorafenib, Bayer), Sutent, (sunitinib, Pfizer) and Votrient (pazopanib, GSK) and these are validated targets.

ENMD-2076 has been previously examined in clinical trials for an array of indications including ovarian cancer, soft tissue sarcoma and multiple myeloma, which have all been discontinued due to insufficient activity. CASI announced in April 2017 that it was halting enrolment in its Phase 2 study in TNBC. Of the 36 patents that were evaluated in the trial, two had partial responses and 14 had stable disease. The company has a Phase IIa study in TNBC ongoing in China.

The company also has ongoing Phase II trial of ENMD-2076 in the US (and CFDA approval to expand to China) for the treatment of advanced fibrolamellar carcinoma (FLC). FLC is an ultra-rare subtype of hepatocellular carcinoma affecting fewer than 100 new patients in the US per year (0.02 per 100,000 incidence).[17] There are currently no pharmacologic treatments approved specifically for FLC, although chemotherapy and checkpoint inhibitors are used in practice. Enrolment in the study is complete (target of 29) and the company has stated that it intends to present data at a medical conference in 2018.

Sensitivities

CASI's risk profile is substantially different to other pre-commercial pharmaceutical companies. The company's business model is based around leveraging the new regulatory environment in China to its advantage, and despite it being on the forefront of recent reforms, this continued rapid change may present unforeseen hurdles for the company. There is little insight into what the priorities of regulators will be in five years' time, although our outlook remains positive. An example of this is the recent news that Evomela has been presented to an advisory committee based on data from US registration trials, following a mandate to allow approval based on these data. However, it is unknown if the current package will be satisfactory and by what standards it will be judged. Moreover, it is unknown if the same pathway will be open to Marqibo and Zevalin or if these will require Phase III studies. Moreover, these drugs face uncertainty over their periods of exclusivity. We expect data exclusivity to provide the majority of protection for both Marqibo and Zevalin, but we do not have the benefit of history to know how these policies will appear in practice.

Other risks to the company are primarily commercial. The primary risk to the Spectrum portfolio is that there will be limited adoption in China, as there has been in the US. However, unlike in the US, Evomela will be the first approval for melphalan, which we expect to substantially improve its market penetration. The portfolio of generic drugs faces the commercial risks typically associated with a generic pharmaceutical business. The generics business is highly competitive and China is one of the most competitive in the world. This will be partially offset by the large markets for the drugs, in particular for HBV, but the company will need to compete with a large number of established competitors in each case.

We consider the company's internal development to be secondary to its Chinese commercial strategy at this time. ENMD-2076 faces considerable commercial risk considering it has not produced a compelling activity profile to date, although we expect future expenditures associated with the program to be limited.

[17] Fibrolamellar Cancer Foundation.

Financial risks are limited following the recent offerings due to the quick pathway to market. However, if the company encounters delays with regulatory authorities or in market preparations, it may need to seek further financing.

Valuation

We arrive at an initial valuation of $754m or $8.06 per basic share. The drugs in the Spectrum portfolio are valued based on a risk-adjusted NPV analysis with a discount rate of 10%. Our estimates use a series of assumptions for each individual product (Exhibit 8). We use the population of Chinese citizens covered under urban insurance plans (UEBMI, URBMI) and citizens in Hong Kong, Macau and Taiwan as a proxy for those with access to care and reimbursement. We may adjust this assumption in the future if there are improvements on these fronts. Across the portfolio we estimate a 5% COGS and 10% cost of selling in addition to $1m of fixed overhead. We estimate R&D costs at $20,000 per patient. We apply a 90% risk adjustment to these programs to encompass potential regulatory hurdles.

Exhibit 8: Assumptions for Spectrum portfolio

Drug	First sales	Exclusivity	Launch price ($)	Notes
Evomela	2019	2029	7,500	Early approval based on foreign data; 35% peak penetration, 20% royalty payable to Ligand
Marqibo	2020	2030	19,800	10% penetration, 60-person clinical study for approval
Zevalin	2020	2030	11,600	20% penetration, 60-person clinical study for approval

Source: Edison Investment Research

For the generics portfolio, we use a DCF model with a 10% discount rate and a 2% terminal growth rate. Our revenue estimates are made on a product-by-product basis for both the US and China and we take into account both the current market size for these products (as reported by Symphony Health) and the relative prevalence of each disorder in China vs the US. On average, we assume pricing in China at 43% of that in the US, although this varies on a drug-to-drug basis. Additionally, we account for previous sales in the US by Sandoz as a benchmark. We estimate an average peak market share of 4% in the US and 2% in China. The highest revenue product is predicted to be Entecavir, with $40m in peak sales (85% in China). We expect the first significant sales in China in 2019 and in the US in 2020. We assume COGS of 30%, which is low due to proposed manufacturing in China, and model $5m in fixed and 10% variable overhead. We expect this overhead to encompass the costs associated with securing and maintaining distribution and administrating delivery of drug. These values are roughly in line with other generics manufacturers in low-cost countries (eg Dr Reddy's has COGS of 24% and labor costs of 17%). We should note that this valuation is highly sensitive to the company's ability to secure distribution in the US and China. A change in market share of 1% (in absolute terms) across the portfolio results in a change in the DCF of $240m.

Our valuation for ENMD-2076 is based on a risk-adjusted NPV analysis with a 20% probability of success. We consider the program high risk due to the limited indications of efficacy. Our valuation is low ($1.4m) primarily due to the small target market. We do not include a value for any other indication this time.

Exhibit 9: Valuation of CASI Pharmaceuticals

Portfolio	Asset	Region	Peak sales ($m)	Margin	Clinical risk adjustment	Value ($m)
Spectrum	Evomela	China	15.4	46%	90%	20.75
	Marqibo	China	8.3	58%	90%	7.97
	Zevalin	China	23.9	64%	90%	47.00
Generics		China & US	249.7	49%	100%	578.17
Internal	ENMD-2076	China & US	25.2	51%	20%	1.43
Total						655.32
Net cash and equivalents (Q218) ($m)						98.53
Total firm value ($m)						753.85
Total shares (m)						93.59
Value per basic share ($)						8.06
Dilutive warrants and options (est.)						31.81
Value per diluted share ($)						6.76

Source: CASI reports, Edison Investment Research

Financials

CASI reported a net loss of $8.8m for Q318. This was driven primarily by G&A expenses ($6.9m), in particular due to preparations for commercial launch in China. We expect a substantial investment in overhead required for the launch of the Spectrum and generics portfolios, which translates into an SG&A spend for 2018 of $18.1m compared to $3.2m in 2017. These SG&A costs include hiring or contracting a salesforce for the Spectrum drugs, maintaining and securing distribution contracts for the generic portfolio, and progressing these assets through the regulatory apparatus.

The company has stated it will be breaking ground on a new production facility in the Wuxi Huishan Economic Development Zone in 2019. We expect this facility to eventually supply drugs from the generic portfolio for the US and China markets. The project will be a joint venture between the company and Wuxi Jintou Huicun Investment Enterprise. CASI will initially commit $21m (and Wuxi will commit $20m) and is committed to an additional $29m within three years, and up to a total of $80m for an 80% stake in the enterprise. We include the initial payments ($21m and $29m) as capex in our model. Additionally CASI will be transferring select ANDAs to the entity. In the near term, we expect CASI to license manufacturing for the generic portfolio, although we expect this to transition to the manufacturing project as it develops. Spectrum will manufacture drugs from its portfolio.

CASI ended Q318 with $100m in gross cash, following the first $37.5m tranche of the September private placement (in total $48.5m: 9.0m shares at $5.36 and 2.7m warrants at $7.19). The company has $1.5m in debt as a promissory note associated with the Spectrum acquisition (at 0.5%) due in September 2019. We do not expect the company to require additional capital before profitability in 2021.

Exhibit 10: Financial summary

$'000s	2016	2017	2018e	2019e
31-December	US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT				
Revenue	0.0	0.0	0.0	9,645.3
Cost of Sales	0.0	0.0	0.0	(2,744.0)
Gross Profit	0.0	0.0	0.0	6,901.3
EBITDA	(6,358.9)	(9,983.1)	(18,433.0)	(10,608.5)
Normalized operating profit	(6,425.4)	(10,100.9)	(18,733.2)	(15,117.2)
Amortization of acquired intangibles	0.0	0.0	(1,291.8)	(1,388.8)
Exceptionals	0.0	0.0	(687.0)	0.0
Share-based payments	(2,995.2)	(650.4)	(5,222.8)	(5,222.8)
Reported operating profit	(9,420.6)	(10,751.3)	(25,934.7)	(21,728.9)
Net Interest	(26.1)	1.0	38.7	0.0
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	(6.8)	(19.9)	(67.3)	0.0
Profit Before Tax (norm)	(6,458.2)	(10,119.8)	(18,761.7)	(15,117.2)
Profit Before Tax (reported)	(9,453.5)	(10,770.2)	(25,963.3)	(21,728.9)
Reported tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(6,458.2)	(10,119.8)	(18,761.7)	(15,117.2)
Profit After Tax (reported)	(9,453.5)	(10,770.2)	(25,963.3)	(21,728.9)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalized)	(6,458.2)	(10,119.8)	(18,761.7)	(15,117.2)
Net income (reported)	(9,453.5)	(10,770.2)	(25,963.3)	(21,728.9)
Basic average number of shares outstanding (m)	56	62	83	95
EPS - basic normalized (c)	(11.56)	(16.45)	(22.61)	(15.84)
EPS - diluted normalized (c)	(11.56)	(16.45)	(22.61)	(15.84)
EPS - basic reported (c)	(16.92)	(17.51)	(31.29)	(22.76)
Dividend (c)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	264.1	1,288.5	39,535.4	33,953.0
Intangible Assets	0.0	0.0	16,763.2	15,374.4
Tangible Assets	229.6	1,046.5	22,543.7	18,350.2
Investments & other	34.5	242.0	228.4	228.4
Current Assets	27,448.8	43,812.4	72,641.3	59,825.0
Stocks	0.0	0.0	0.0	676.6
Debtors	0.0	0.0	0.0	1,585.5
Cash & cash equivalents	27,092.9	43,489.9	71,297.6	56,219.2
Other	355.9	322.5	1,343.7	1,343.7
Current Liabilities	(1,315.6)	(5,062.1)	(6,022.9)	(4,130.4)
Creditors	(1,064.6)	(4,316.1)	(3,722.7)	(3,329.4)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	0.0	(1,499.3)	0.0
Other	(251.0)	(746.0)	(801.0)	(801.0)
Long Term Liabilities	(5,613.5)	(1,498.8)	0.0	0.0
Long term borrowings	(1,491.3)	(1,498.8)	0.0	0.0
Other long term liabilities	(4,122.3)	0.0	0.0	0.0
Net Assets	20,783.8	38,540.1	106,153.7	89,647.6
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	20,783.8	38,540.1	106,153.7	89,647.6
CASH FLOW				
Op Cash Flow before WC and tax	(6,358.9)	(9,983.1)	(18,433.0)	(10,608.5)
Working capital	348.0	3,572.4	(1,055.7)	(2,655.4)
Exceptional & other	(12.2)	8.5	44.6	0.0
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(6,023.1)	(6,402.2)	(19,444.0)	(13,263.9)
Capex	(64.8)	(934.7)	(21,861.1)	(315.2)
Acquisitions/disposals	0.0	0.0	(19,172.0)	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	28,049.7	23,733.9	89,580.4	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	(117.2)	0.0
Net Cash Flow	21,961.8	16,397.0	28,986.2	(13,579.1)
Opening net debt/(cash)	(3,639.8)	(25,601.7)	(41,991.7)	(69,798.3)
FX	0.0	0.0	(1,178.5)	0.0
Other non-cash movements	0.0	(7.0)	(1.0)	0.0
Closing net debt/(cash)	(25,601.7)	(41,991.7)	(69,798.3)	(56,219.2)

Source: Company accounts, Edison Investment Research

Contact details	Revenue by geography
9620 Medical Center Drive Suite 300 Rockville, MD 2085 USA (240) 864-2600 www.casipharmaceuticals.com	N/A

Management team

CEO: Ken K Ren

Dr Ren joined CASI Pharmaceuticals in April 2012, was appointed CEO in April 2013 and elected to the board of directors in December 2014. Over the past 15 years, prior to CASI, Dr Ren has been a founder and/or key executive in several start-up companies with business operations in both the U.S. and China. He was president of Accelovance (China), a clinical contract research organization, a co-founder and CEO of ImmunoVentis, a cell-based immunotherapy company, Novemed, a drug development company, and of China Innovation Center for Life Science (USA, a consulting company. Dr Ren was also a chief investment director of CCBI Healthcare Fund of China Construction Bank, responsible for private equity investment in China's healthcare industry.

General counsel & secretary: Cynthia W Hu

Ms Hu joined CASI Pharmaceuticals in June 2006 as vice president, general counsel & secretary, and in December 2008 was appointed chief operating officer. Prior to joining CASI Pharmaceuticals, from January 2000 to May 2006, Ms Hu served as senior attorney for the corporate and finance practice group at Powell Goldstein in Washington, DC. Before that, Ms Hu served as corporate and securities counsel for a NYSE-listed financial institution and prior to that was in private practice with increasing levels of responsibilities, including at Klehr, Harrison, Harvey & Branzburg and Littman & Krooks focusing on corporate transactions and compliance with corporate and securities laws.

CMO: Alexander A Zukiwski

Dr Zukiwski joined CASI Pharmaceuticals in April 2017 as chief medical officer. Prior to joining CASI Pharmaceuticals Dr. Zukiwski was chief executive officer and chief medical officer of Arno Therapeutics and has been a director of Arno Therapeutics since 2014. At Arno his responsibilities included leading the clinical development and regulatory affairs teams to support the company's pipeline. Prior to Arno in 2007, Dr Zukiwski served as chief medical officer and executive vice president of Clinical Research at MedImmune. Prior to MedImmune, Dr Zukiwski held several roles of increasing responsibility at Johnson & Johnson's (J&J,) medical affairs and clinical development functions at J&J Pharmaceutical Research & Development, Centocor R&D and Ortho Biotech.

CFO: George Chi

Mr Chi joined CASI Pharmaceuticals in October 2018 as chief financial officer. Prior to joining CASI, Mr Chi was VP of finance at Flavor Holdings where he led the global accounting function, including financial reporting, planning, treasury, investor relations, tax and auditing with global sales in 90 countries. Prior to Flavor Holdings, from 2014 to 2016, he was CFO at BPL Plasma, delivering 60% sales growth and 300% EBITDA growth for a $180m business. He consolidated business and finance operations to prepare for an IPO, where the business was sold for four times the investment in three years.

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Spectrum Pharmaceuticals	12.3
Sparkle Byte	10.9
Kung Hung Ka	9.2
IDG-Accel China Investors LP	9.1
Emerging Technology Partners LLC	5.8
Zhejiang Kanglaite Group Co	5.3
BlackRock Inc	3.1
Vanguard Group	2.1
Wellington Shields	1.0
Wei-Wu He	0.9

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