

# Biotechnology

# Antibiotic and Antifungal Update: August 2020

Developments since our last update on the space include positive results from Phase 3 trials of ibrexafungerp by Scynexis (SCYX BUY), Exblifep by Allecra, and SER-109 by Seres. Other events included mixed results from two more Phase 3 trials of sulopenem by Iterum, a disruption of the Xenleta launch by COVID-19 that led Nabriva (NBRV HOLD) to change its sales force, and the sale of Tetraphase to La Jolla. With respect to policy, legislation is being drafted that provides post-approval funding to industry (PASTEUR bill), but we believe this may not necessarily benefit investors and patients. We continue to believe reimbursement reform in the hospital setting (DISARM bill) and more frequent medical society guideline updates are prerequisites for a turnaround in the space. Most global Pharma companies announced participation in the \$1B AMR Action Fund in July 2020 to support R&D at smaller companies. Although the announcement had minimal impact on stock prices in the space, we believe the new fund serves as evidence of Pharma commitment to infectious diseases and may persuade the U.S. to pass supportive legislation.

- Antibiotic and Antifungal Sales Patterns: Branded antibiotic and antifungal sales data are shown in Table 1 and Figures 1 and 2. In some cases, there is evidence of a spike in sales in March. On the other hand, every drug experienced a decline in sales from March to April, exceeding what was seen during the same period in 2019. Our Iqvia data reflect supply, not demand, and therefore increases in March may reflect stockpiling, followed by a decline in inventory the subsequent month.
- Antibiotic Launches and Regulatory Decisions: Nabriva terminated its hospital sales force in April due to COVID-19 and announced plans in July to hire a contract sales force focused on the community. The company also recently reached an agreement with Merck to market Sivextro in the U.S. A relaunch is planned for September. We believe the strategic decisions are appropriate, but remain concerned by the financial constraints the company is facing. The FDA issued a Complete Response Letter for Contepo due to an inability to conduct a facility inspection in Europe because of COVID-19. Shionogi launched Fetroja in February and announced an sNDA filing in HABP/VABP (PDUFA 9/27/20). Merck launched Recarbrio in January and announced FDA label expansion to HABP/VABP in June.
- Antibiotic Phase 3 Updates: All Iterum Phase 3 trials narrowly missed primary noninferiority endpoints, but did establish superiority of oral sulopenem over ciprofloxacin in uUTI patients with ciprofloxacin-resistant infections. Discussions with FDA are planned. Seres recently announced the Phase 3 ECOSPOR III trial met the primary endpoint of reduction in *C. difficile* infection recurrence at 8 weeks (41.3% vs. 11.1%). Spero may have oral tebipenem Phase 3 ADAPT-PO results in cUTI in 3Q20. Basilea (ERADICATE), Contrafect (DISRUPT), Entasis (ATTACK), Summit, and Venatorx may have Phase 3 results in 2021. Qpex has not yet advanced its broad spectrum IV/oral betalactamase inhibitors into Phase 3.
- Antifungal R&D Updates: Scynexis announced positive results from Phase 3 trials of ibrexafungerp in acute Vulvovaginal Candidiasis and plans to submit an NDA in 4Q20. We believe there is a substantial disconnect between valuation and near-term revenue opportunity. Cidara (BUY) initiated the Phase 3 RESPECT prophylaxis trial in transplant patients in May. We expect a positive outcome from the Phase 3 RESTORE treatment trial, which is already underway, in 2021. Amplyx announced encouraging data from a Phase 2 trial of fosmanogepix in Invasive *Candida* infections in June and results from a Phase 2 *Aspergillus* trial may be available YE20. F2G continues to enroll patients with a variety of rare/ resistant mold infections in a Phase 2 trial, with impressive responses to

#### **RELEVANT DISCLOSURES BEGIN ON PAGE 9 OF THIS REPORT.**

### **Topic of Discussion**

Update on the Antibiotic and Antifungal Landscape with Prescription and Sales Data

#### **CONTRIBUTING ANALYSTS**

ALAN CARR, PH.D., CFA (212) 705-0435 acarr@needhamco.com

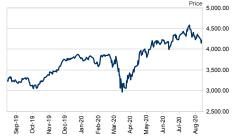
JOSEPH STRINGER, PH.D. (212) 705-0346 jstringer@needhamco.com

#### **MENTIONED COMPANIES**

**CDTX**: \$3.78, PT: \$6.00 **NBRV**: \$0.68, PT: NA **SCYX**: \$6.77, PT: \$50.00

### **SECTOR CHART**





# Needham

date. Mycovia may announce results from Phase 3 trials of oteseconazole in recurrent VVC in 2H20.

- Policy: We believe one of the most important challenges for the space is the financial disincentive around use in the hospital setting (CMS Part A). Legislation addressing this issue is a prerequisite for restoring investor interest in our opinion. We do not believe legislation that provides direct funding to the company after approval (e.g. subscription model or market entry reward) will necessarily be helpful unless the barrier at the hospital level is also addressed.
- AMR Action Fund: Over 20 companies have contributed a total of \$1B to a fund intended to invest in 12-20 biotech companies over a 10-year period. The focus will be on companies with Phase 2-ready programs and the goal is to bring 2-4 new antibiotics to market by 2030.
- Transactions and Financial Updates: Aradigm was acquired for \$3.2M by Grifols in February, with \$3M in earn-out payments and 25% royalties. Melinta completed a restructuring in April and is now a private company. Tetraphase was acquired in July by La Jolla for \$43M upfront and up to \$16M in earn-out payments. Cidara and Spero each raised \$30M in rights offerings in February and March. Contrafect raised \$52M in a May public offering. Nabriva raised \$38M in a registered direct offering in May. Entasis raised \$35M in a June private placement. Amplyx raised \$53M in May and F2G raised \$60M in August.



# **BRANDED ANTIBIOTIC AND ANTIFUNGAL SALES DATA**

U.S. sales as reported by Iqvia are shown below. Actual sales figures are available from a limited number of companies and may differ from Iqvia data. See Table 3 for sales data as reported by individual companies.

	AVY	BAX	CRE	DAL	DIF	FET	MIN	NUZ	ORB	REC	SIV	TEF	VAB	VIB	XER	ZEM	ZER	ZIN
Jan-16	2.6	-	2.1	1.1	6.1	-	0.5	-	0.7	-	0.7	9.7	-	1.2	-	-	1.2	-
Feb-16	3.1	-	2.4	1.6	5.9	-	0.4	-	0.9	-	1.0	10.2	-	1.4	-	-	1.3	-
Mar-16	3.9	-	3.0	2.5	7.5	-	0.9	-	1.0	-	1.3	14.5	-	1.8	-	-	1.7	-
Apr-16	3.5	-	2.9	1.8	6.0	-	0.5	-	1.0	-	1.0	11.2	-	1.6	-	-	1.3	-
May-16	3.9	-	4.4	2.3	6.4	-	0.6	-	1.2	-	1.0	11.0	-	1.7	-	-	1.5	-
Jun-16	5.1	-	4.2	3.2	7.6	-	0.9	-	1.4	-	1.0	13.5	-	2.2	-	-	1.9	-
Jul-16	5.1	-	3.2	2.3	6.0	-	0.6	-	0.9	-	1.0	10.3	-	1.6	-	-	1.5	-
Aug-16	0.8	-	3.8	2.6	6.3	-	0.7	-	1.2	-	1.0	10.2	-	1.5	-	-	1.9	-
Sep-16	0.3	-	4.9	3.5	7.8	-	0.8	-	1.6	-	1.4	13.5	-	2.0	-	-	2.3	-
Oct-16	0.1	-	4.2	2.9	6.2	-	0.7	-	1.0	-	1.0	10.1	-	2.0	-	-	2.1	-
Nov-16	0.1	-	4.4	2.8	6.5	-	0.6	-	1.2	-	0.9	9.9	-	1.5	-	-	2.4	-
Dec-16	3.4 2.7	-	5.8 4.8	3.7 2.6	7.4 5.7	-	0.9	-	1.5 1.0	-	1.3 1.0	13.0 9.9	-	1.8 1.2	-	-	2.8 2.0	-
Jan-17 Feb-17	3.2	-	4.0 5.2	2.0	6.4	-	0.7	-	1.0	-	1.0	10.6	-	1.2	-	-	2.0	- 0.0
Mar-17	4.5	-	6.2	4.0	7.8	-	0.7	-	1.2	-	1.5	13.3	-	2.0	-	-	2.3	0.0
Apr-17	4.5	-	5.5	3.4	6.4	-	0.9	-	1.3	-	1.0	10.2	-	1.4	-	-	2.0	0.1
May-17	4.2	_	5.9	3.7	6.4	-	0.7	-	1.2	_	1.5	10.2	-	1.4	-	-	2.4	0.3
Jun-17	5.7	_	8.1	5.1	8.6		0.7	_	1.3	_	2.0	12.9	_	1.4	-	_	3.0	0.3
Jul-17	4.6	-	6.1	3.7	6.3	-	0.7	-	1.0	-	1.6	9.9	-	1.6	-	_	2.4	0.2
Aug-17	4.5	-	6.5	4.2	6.4	-	0.8	-	1.6	-	1.8	9.3	-	1.6	-	-	2.4	0.4
Sep-17	6.1	-	8.7	5.7	8.1	-	1.1	-	2.1	-	2.4	12.3	-	1.6	-	-	3.0	0.5
Oct-17	4.6	-	6.8	5.0	6.2	-	0.8	-	1.5	-	1.9	9.3	0.0	1.4	-	-	3.0	0.4
Nov-17	5.0	-	7.3	0.8	6.2	-	0.9	-	1.8	-	2.0	9.0	0.1	1.3	-	-	3.0	0.4
Dec-17	7.0	-	9.9	5.6	7.5	-	0.9	-	2.5	-	2.4	12.9	0.2	1.7	-	-	4.1	0.5
Jan-18	5.5	0.9	8.3	3.1	6.0	-	0.9	-	1.5	-	1.6	10.9	0.2	1.1	-	-	2.9	0.3
Feb-18	6.1	0.1	8.0	3.6	6.4	-	0.9	-	1.8	-	2.0	11.7	0.4	1.5	-	-	3.0	0.5
Mar-18	8.1	0.2	10.5	5.6	9.3	-	1.0	-	2.2	-	2.8	13.4	0.6	2.1	-	-	3.9	0.7
Apr-18	6.0	0.3	8.5	5.2	8.9	-	0.9	-	1.6	-	2.5	10.5	0.4	1.8	-	-	3.1	0.5
May-18	6.6	0.4	8.9	4.2	9.0	-	0.9	-	1.5	-	2.7	11.1	0.4	2.1	-	-	3.0	0.6
Jun-18	8.4	0.6	11.3	5.5	11.8	-	1.1	-	1.9	-	4.2	12.7	0.8	2.2	-	-	4.0	0.6
Jul-18	6.6	0.5	9.0	4.4	9.3	-	0.9	-	1.7	-	3.6	10.6	1.0	1.7	-	0.0	3.5	0.7
Aug-18	7.4	0.7	9.6	4.9	9.7	-	0.8	-	1.9	-	4.0	10.4	0.5	1.6	-	0.1	3.8	0.6
Sep-18	9.6	1.1	12.4	7.7	12.1	-	1.2	-	2.5	-	5.1	12.2	0.7	2.2	-	0.1	4.6	0.7
Oct-18	7.4	0.9	10.2	3.8	10.1	-	0.8	-	3.2	-	3.8	11.0	0.7	2.0	0.0	0.0	3.9	0.6
Nov-18	7.7	0.9	9.7 12.9	5.5 4.5	9.1	-	0.8	-	2.4	-	3.3 3.6	10.8	0.7 0.9	1.8 2.0	0.0	0.1	3.9 4.9	0.6
Dec-18 Jan-19	10.1 8.3	1.1 0.7	12.9	3.8	10.6 9.3	-	0.8	-	1.6	-	2.8	13.0 11.7	0.9	2.0	0.1	0.1	4.9	0.7
Feb-19	8.2	0.7	9.5	3.0	9.3 9.4	-	1.1	0.7	1.0	-	2.0	11.7	1.0	1.2	0.1	0.1	4.2	0.5
Mar-19	10.8	1.1	12.9	4.6	12.2	-	1.1	0.7	2.4	-	3.7	14.2	1.0	1.5	0.1	0.1	5.4	0.6
Apr-19	7.4	0.9	12.9	5.0	10.0		0.9	0.2	1.7	_	3.4	14.2	0.9	1.0	0.2	0.1	4.1	0.6
May-19	8.0	1.1	10.4	5.7	10.1	-	0.9	0.6	2.2	-	3.7	11.6	1.1	1.1	0.3	0.1	4.2	0.7
Jun-19	10.5	1.5	13.6	6.2	12.3	-	1.2	0.6	2.7	-	4.8	14.5	1.4	1.4	0.4	0.1	6.0	0.7
Jul-19	8.1	1.3	11.6	5.1	9.8	-	0.8	0.7	2.1	-	4.5	12.0	1.1	1.1	0.3	0.0	6.2	0.7
Aug-19	8.1	1.4	11.6	5.8	10.9	-	1.0	0.7	2.0	-	5.1	11.4	1.1	1.0	0.4	0.0	5.6	0.6
Sep-19	11.6	2.0	14.3	7.4	12.9	-	1.3	1.4	2.8	-	5.8	13.9	1.5	1.3	0.4	0.0	7.0	0.9
Oct-19	8.6	1.7	12.9	7.9	11.5	-	1.0	1.2	2.0	-	5.1	11.5	1.4	0.9	0.5	0.0	5.8	0.7
Nov-19	9.0	1.3	12.4	8.2	11.4	-	1.1	1.6	1.8	-	3.9	11.6	1.6	0.9	0.5	0.0	6.2	0.9
Dec-19	10.7	1.0	16.1	8.8	12.6	-	1.2	1.8	2.1	-	4.4	13.7	1.7	1.2	0.6	0.0	7.1	0.8
Jan-20	8.6	0.6	13.0	6.5	10.5	-	1.1	1.6	1.4	0.0	2.6	11.2	1.1	0.9	0.5	0.0	6.1	0.7
Feb-20	9.4	0.5	12.1	7.0	10.1	0.0	0.8	1.9	1.4	0.2	2.5	12.0	1.9	1.0	0.7	0.0	6.1	0.7
Mar-20		0.6	16.6	10.2	13.9	0.5	1.2	3.3	1.9	0.4	3.2	16.0	3.3	1.0	0.8	0.0	8.3	0.7
Apr-20		0.4	11.5	6.4	8.6	0.3	0.9	2.1	1.3	0.3	2.7	9.4	1.9	0.6	0.5	0.0	5.7	0.4
May-20		0.3	11.8	6.0	8.3	0.3	1.0	2.4	1.2	0.1	1.9	9.2	1.7	0.7	0.6	0.0	6.1	0.5
Jun-20		0.4	15.6	10.0	10.6	0.5	1.2	3.2	1.6	0.3	3.1	12.2	2.0	0.6	0.8	0.0	8.3	0.6
L12M		11.7	159.7	89.3	131.1	1.7	12.6	21.9	21.7	1.3	44.8	144.2	20.3	11.2	6.4	0.4	78.4	8.3

Source: IQVIA; AVY Avycax BAX Baxdela; CRE Cresemba DAL Dalvance DIF Dificid FET Fetroja MIN Minocin NUZ Nuzyra ORB Orbactiv REC Recarbrio SIV Sivextro TEF Teflaro VAB Vabomere VIB Vibativ XER Xerava ZEM Zemdri ZER Zerbaxa ZIN Zinplava



Figure 1 - Monthly Iqvia Sales Data (\$M; Unadjusted)

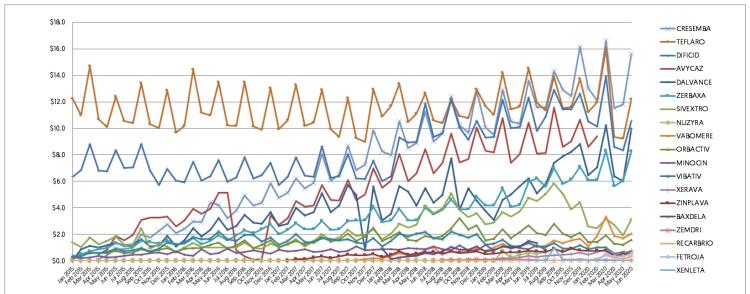
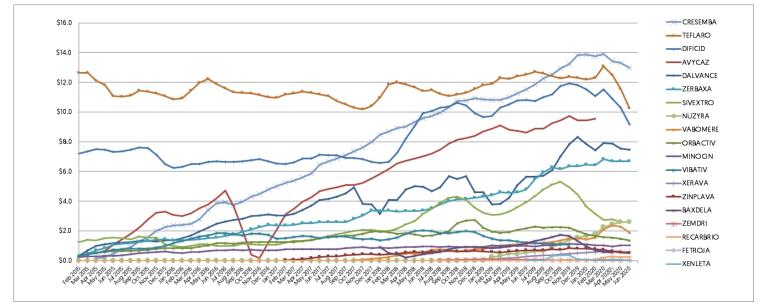


Figure 2 - Monthly Iqvia Sales Data (\$M; 3-Month Ave)





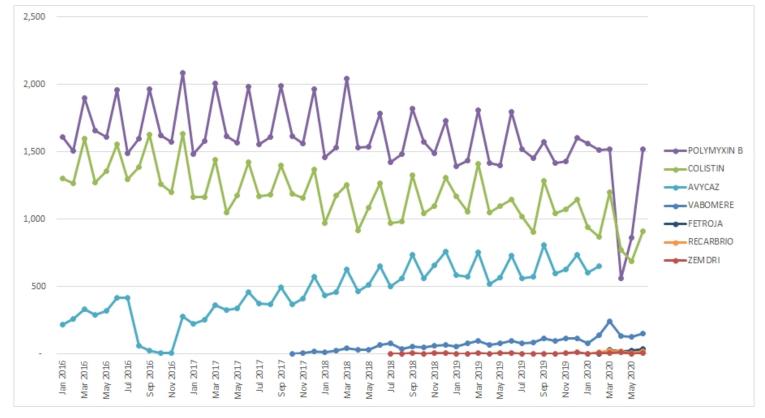
# CARBAPENEM RESISTANT ENTEROBACTERIACEAE (CRE) MARKET

Challenging infections caused by CRE have typically been treated with colistin (also known as polymyxin E), polymyxin B, tigecycline, aminoglycosides, high dose carbapenems, or combinations thereof. Several new drugs with safety and/or efficacy advantages have reached the market in recent years. Avycaz was approved in the U.S. in 2015, followed by Vabomere in 2017, Zemdri in 2018, and Recarbrio and Fetroja in 2019.

We have attempted to model the market in our reports over the past few years using data from Iqvia (eaches=vials). Our estimates of the number of courses of treatments in the CRE market are shown below (Figure 3). Evidence suggests that adoption of the new drugs has been relatively slow, despite advantages over older drugs. Our belief is that there has been an underlying shift in the treatment of CRE away from colistin primarily to Avycaz and polymyxin B.

We acknowledge critical limitations of our analysis, including the fact that colistin and polymyxin B are also used against infections caused by other pathogens, in particular *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. Additionally, colistin is also inhaled by Cystic Fibrosis patients. We have removed certain channels from our colistin estimates in an attempt to exclude inhaled use by this patient group (Chain stores; Food stores; Independent pharmacies, and Mail order). Lastly, the method of physical distribution of Avycaz changed in 1Q20 and sales data are no longer available from Iqvia. We therefore believe it will be a challenge to model this market going forward.

COVID-19 had a significant impact on sales, including a spike for Vabomere in March and a profound drop for polymyxin B in April.



### Figure 3 - Sales of Drugs Relevant to the CRE Market (Treatment course estimates)



# **Table 1 - Antimicrobial Company Valuations**

TICKER	F	PRICE	ļ	52 HI	52 LO	YTD	2019	2018	MKT CAP	EV	CASH	L12M	DEBT	DEVELOPMENT
						RETURN	RETURN	RETURN	\$M	\$M	\$M	OPEX	\$M	STATUS
BSLN-SWX	\$	50.90	\$	61.20	\$ 29.28	5%	17%	-47%	606.7	701.1	114.7	146.7	209.1	Market
CDTX	\$	3.78	\$	4.45	\$ 1.22	5%	63%	-65%	155.4	81.8	74.3	63.3	0.7	Phase 3 Underway
CFRX	\$	5.40	\$	13.40	\$ 2.69	-13%	-59%	51%	146.5	133.0	16.7	29.6	3.2	Phase 3 Underway
ETTX	\$	2.91	\$	9.25	\$ 1.75	-41%	22%		42.5	(7.2)	50.8	54.5	1.0	Phase 3 Underway
INSM	\$	29.58	\$	34.94	\$ 12.09	21%	82%	-58%	2,945.5	2,693.6	641.9	382.0	390.0	Market
ITRM	\$	0.89	\$	7.65	\$ 0.92	-78%	-10%		18.9	45.8	12.3	75.6	39.2	Phase 3 Complete
MCRB	\$	23.56	\$	33.00	\$ 2.52	481%	-24%	-55%	1,796.7	1,770.8	63.9	105.5	38.0	Phase 2/3 Complete
NBRV	\$	0.68	\$	2.77	\$ 0.49	-45%	-10%	-76%	97.6	55.0	50.1	82.7	7.5	Market
PRTK	\$	4.30	\$	6.41	\$ 2.50	8%	-21%	-71%	185.5	250.4	188.2	124.4	253.2	Market
SCYX	\$	6.77	\$	14.40	\$ 5.00	-25%	89%	-79%	66.9	50.9	37.6	50.2	21.6	Phase 3 Complete
SMMT	\$	3.49	\$	5.49	\$ 1.18	121%	39%	-90%	46.9	29.3	17.6	55.7	-	Phase 3 Underway
SPRO	\$	12.66	\$	14.48	\$ 5.25	35%	56%	-48%	260.7	194.0	71.4	96.9	4.6	Phase 3 Underway
SYN	\$	0.56	\$	0.75	\$ 0.25	17%	-9%	-97%	10.2	2.5	8.1	14.4	0.3	Phase 2
NBI	\$	4,203.06	\$ 4	4,600.54	\$ 2,947.85	9%	24%	-9%						
MAX						481%	89%	51%						
MEAN						30%	0%	-63%						
MEDIAN						5%	-10%	-71%						
MIN						-78%	-88%	-97%						

Source: Factset Data; Factset Consensus Revenue Ests



### Table 2 - BRANDED ANTIBIOTIC AND ANTIFUNGAL PRICING AND SALES (U.S. ONLY)

Drug Company	Unit	WAC	Dosage	WAC/Course*	Price Change	U.S. Sales
Ambisome Astellas	1x50mg Vial	\$260	3-5mg/kg qd	\$25,935 5mg/kg	5% increase 1/1/2020	2Q20 Iqvia sales \$24.9M 2Q20 Astellas Report \$22M
Arikayce	28x 590mg	\$11,626	590mg qd	14 days \$139,512	6% increase 1/1/2020	2Q20 Iqvia sales \$1.1M
nsmed Avycaz	Vial 1x2.5g	\$359	cIAI 2.5g q8h, 5-14 days	\$5387-15085	9.5% increase 1/1/2019	2Q20 Insmed Report \$42.5M
Abbvie Baxdela	Vial 10x300mg	\$1,325	cUTI 2.5g q8h, 7-14 days 300mg q12h	\$1325-3710	Launch price	Abbvie acquired Allergan 2Q20 Iqvia sales: \$1.2M
/lelinta	Vial 20x450mg Tablet	\$1,488	5-14 days 450mg q12h	\$781-2188	10/20/2017 5% increase	
Cresemba	1x372mg Vial	\$315	5-14 days 372mg q8h load 2days	\$15,400	4/1/2019 6% increase 1/8/2019	2Q20 Iqvia sales: \$39.0M
Astellas	14x186mg Tablet	\$1,296	372mg qd 372mg q8h load 2days	45 days \$9,257	6% increase	2Q20 Astellas Report \$36M
)alvance	1x500mg Vial	\$1,581	372mg qd 1500mg or	45 days \$4,743	1/8/2019 3% increase 1/3/2020	2Q20 Iqvia sales: \$22.4M
Abbvie Dificid	20x200mg Tablet	\$4,059	1000mg followed one week later by 500mg 200mg oral q12h	\$4,058 10 days	5% increase 1/3/2020	Abbvie acquired Allergan 2Q20 Iqvia sales: \$27.5M
Verck Fraxis Pfizer	1x100mg Vial	\$180	10-14 days 200mg load; 100mg qd 14 days after + culture	\$2,880 15 days	Launch price 10/26/2009	2Q20 Iqvia sales: \$2.6M
Fetroja Shionogi	1x 1g Vial	\$183	2g q8h 7-14 days	15,400 14 days	Launch price 2/24/2020	
Minocin Melinta	1x100mg Vial	\$162	100mg q12h 10-14 days	\$3240-4536	5% increase 8/24/2018	2Q20 Iqvia sales \$3.0M
Noxafil Noxafil Nerck	1x300mg Vial	\$530	300mg BID Load; 300mg QD		Launch price 3/18/2014	2Q20 Iqvia sales: \$14.0M 2Q20 MRK Report \$73M
NEICK	60x100mg Tablet	\$4,112	300mg BID Load; 300mg QD	\$16,600 80 days	5% increase 1/4/2019	
Nuzyra Paratek	1x100mg Vial	\$355	CABP: 200mg IV load 1 day 100mg IV or 300mg oral QD 7-14 days total ABSSSI: 200mg IV load 1 day or 450mg oral load 2 days 100mg IV or 300mg oral	CABP 7-14days \$3,192-6,088 ABSSSI 7-14day \$3192-6,205	3% increase 7/1/2020	2Q20 lqvia sales: \$7.8M 2Q20 PRTK Report \$8.1M
	6x150mg Tablet	\$1,241	7-14 days total		5% increase 7/1/2020	
Drbactiv Aelinta	1x400mg Vial	\$996	1200mg single dose	\$2,988	3% increase 7/2/2018	2Q20 Iqvia sales: \$4.1M
lecarbrio Verck	1x1.25g Vial	\$268	1.25g q6h	\$12,864 12 days	Launch price 1/6/2020	2Q20 Iqvia sales \$0.7M
ivextro Nerck	10x200mg Vial 6x200mg Tablet	\$3,077 \$2,317	200mg qd for 6 days 200mg qd for 6 days	\$1,846 \$2,318	3% increase 1/3/2020 3% increase 1/3/2020	2Q20 Iqvia sales: \$7.8M
eflaro Abbvie	10x600 mg Vial	\$2,017	600mg q12h 5-14 days	\$2018-5650	5% increase 1/3/2020	2Q20 Iqvia sales: \$30.8M Abbvie acquired Allergan
/abomere /lelinta	1x2.0g Vial	\$165	4.0g q8h 5-14 days	\$4950-13860	Launch price 9/25/2017	2Q20 Iqvia sales: \$5.6M
'ibativ Cumberland	1x750mg Vial	\$479	10mg/kg qd 7-14 days	\$3353-6706	2.5% increase 4/30/2020	2Q20 Iqvia sales: \$1.9M
(enleta Jabriva	1x150mg Vial 30x500mg Tablet	\$102 \$4,125	150mg q12h 5-7 days 600mg q12h 5 days	\$1025-1435 \$1,375	Launch price 9/1/2019	2Q20 Iqvia sales \$0.1M
(erava* etraphase	1x50mg Vial	\$49	1mg/kg q12h 4-14 days	\$785-2750 4-14 days	12% increase 5/30/2019	2Q20 Iqvia sales: \$1.8M
čemdri* Cipla	1x500mg Vial	\$315	15mg/kg qd 4-7 days cUTI	\$3780-13230 4-14 days	Launch price 7/17/2018	2Q20 Iqvia sales: \$0.1M
lerbaxa	10x1.5g	\$1,252	cIAI 1.5g q8h, 4-14 days	\$1504-10525	10% increase 1/3/2020	2Q20 Iqvia sales: \$20.0M
/erck	Vial		cUTI 1.5g q8h, 7 days HABP 3.0g q8h 14 days	4-14 days		2Q20 MRK Report: \$32M

Source: Company reports: Needham & Company, LLC estimates: \*Assume 75-80kg for weight-based dosing and batching; IMS/Iqvia, Symphony Relelbactam: average treatment duration in RESTORE IMI 1 trial was 11.4 days



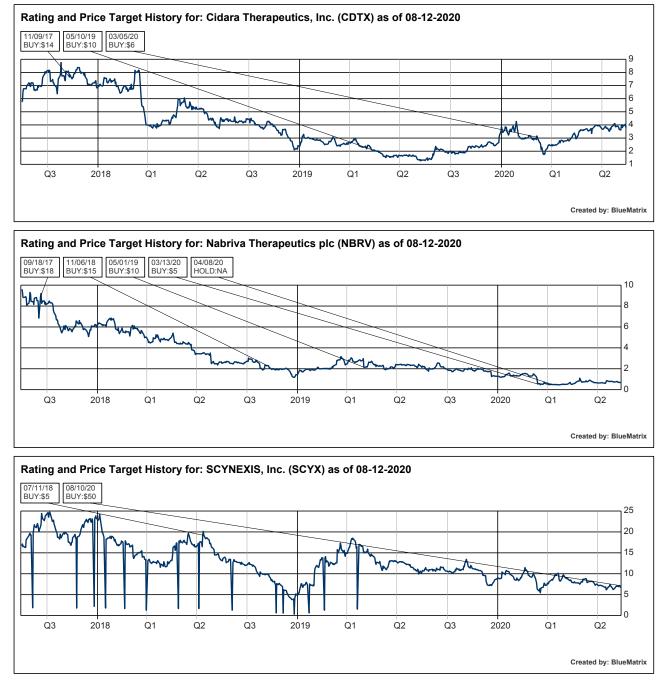
# **RISKS**

Development Risk: The products under development may fail to demonstrate efficacy in clinical trials.

Regulatory Risk: The products under development may not obtain marketing approval from regulatory agencies.

Commercialization Risk: The companies described within this report may not be successful in commercializing products and may be unable to generate sufficient revenue to continue operations.

Financial Risk: The companies described within this report may have insufficient funds to complete product development.



# ANALYST CERTIFICATION

Needham

I, Alan Carr hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company (ies) and its (their) securities. I, also certify that I, have not been, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.



## RATINGS DISTRIBUTIONS FOR NEEDHAM & COMPANY, LLC

	% of companies under coverage with this rating	% for which investment banking services have been provided for in the past 12 months
Strong Buy	2	14
Buy	71	24
Hold	26	2
Underperform	<1	0
Rating Suspended	<1	100
Restricted	<1	0

Needham & Company, LLC employs a rating system based on the following:

Strong Buy: A security, which at the time the rating is instituted, we expect to outperform the average total return of the broader market as well as the securities in the analyst's coverage universe over the next 12 months.

Buy: A security, which at the time the rating is instituted, we expect to outperform the average total return of the broader market over the next 12 months.

Hold: A security, which at the time the rating is instituted, we expect to perform approximately in line with the average total return of the broader market over the next 12 months.

Underperform: A security, which at the time the rating is instituted, we expect to underperform the average total return of the broader market over the next 12 months.

<u>Rating Suspended:</u> We have suspended the rating and/or price target, if any, for this security, because there is not a sufficient fundamental basis for determining a rating or price target. The previous rating and price target, if any, are no longer in effect and should not be relied upon. This rating also includes the previous designation of "Under Review".

<u>Restricted</u>: Needham & Company, LLC policy and/or applicable law and regulations preclude certain types of communications, including an investment recommendation, during the course of Needham & Company, LLC's engagement in an investment banking transaction and in certain other circumstances.

For disclosure purposes, in accordance with FINRA requirements, please note that our Strong Buy and Buy ratings most closely correspond to a "Buy" recommendation. When combined, 73% of companies under coverage would have a "Buy" rating and 24% have had investment banking services provided within the past 12 months. Hold ratings mostly correspond to a "Hold/Neutral" recommendation; while our Underperform rating closely corresponds to the "Sell" recommendation required by the FINRA.

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a security and its implied price appreciation may not correspond to the stated 12-month price target. For valuation methods used to determine our price targets and risks related to our price targets, please contact your Needham & Company, LLC salesperson for a copy of the most recent research report.

Price charts and rating histories for companies under coverage and discussed in this report are available at <u>http://www.needhamco.com/</u>. You may also request this information by writing to: Needham & Company, LLC, Attn: Compliance/Research, 250 Park Ave., New York, NY 10177

By issuing this research report, each Needham & Company, LLC analyst and associate whose name appears within this report hereby certifies that (i) the recommendations and opinions expressed in the research report accurately reflect the research analyst's and associate's personal views about any and all of the subject securities or issuers discussed herein and (ii) no part of the research analyst's or associate's compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst or associate in the research report.

### DISCLOSURES

The research analyst and research associate have received compensation based upon various factors, including quality of research, investor client feedback, and the Firm's overall revenues, which includes investment banking revenues for the following: Cidara Therapeutics, Inc., Nabriva Therapeutics plc and SCYNEXIS, Inc.

The Firm, at the time of publication, makes a market in the subject companies Cidara Therapeutics, Inc., Nabriva Therapeutics plc and SCYNEXIS, Inc..

This report is for informational purposes only and does not constitute a solicitation or an offer to buy or sell any securities mentioned herein. Information contained in this report has been obtained from sources believed to be reliable, but Needham & Company, LLC makes no representation as to its accuracy or completeness, except with respect to the Disclosure Section of the report. Any opinions expressed herein reflect our judgment as of the date of the materials and are subject to change without notice. The securities discussed in this report may not be suitable for all investors and are not intended as recommendations of particular securities, financial instruments or strategies to particular clients. Investors must make their own investment decisions based on their financial situations and investment objectives. The value of income from your investment may vary because of changes in interest rates, changes in the financial and operational conditions of the securities discussed in this report may be volatile. Due to industry, company and overall market risk and volatility, at the securities current price, our investment rating may not correspond to the stated price target. Additional information regarding the securities mentioned in this report is available upon request. (© Copyright 2019, Needham & Company, LLC, Member FINRA, SIPC.