

COMPANY NOTE | EQUITY RESEARCH | March 04, 2020

Healthcare: Biotechnology

Arcturus Therapeutics Holdings, Inc. | ARCT - \$14.50 - NASDAQ | Buy

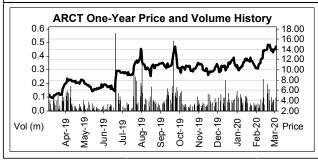
Company Update

Target Price Changed

Stock Data	
52-Week Low - High	\$4.26 - \$15.65
Shares Out. (mil)	15.14
Mkt. Cap.(mil)	\$219.50
3-Mo. Avg. Vol.	81,671
12-Mo.Price Target	\$24.00
Cash (mil)	\$74.2
Tot. Debt (mil)	\$10.0

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Yr Dec	—2018—	—2019E—	—2020E—
		Curr	Curr
1Q	(0.66)A	(0.68)A	(0.66)E
2Q	(0.99)A	(0.07)A	(0.63)E
3Q	(0.42)A	(0.56)A	(0.63)E
4Q	(0.10)A	(0.52)E	(0.65)E
YEAR	(2.16)A	(1.83)E	(2.58)E
P/E	NM	NM	NM

Revenue (\$ millions)												
Yr Dec	—2018—	—2019E—	—2020E—									
		Curr	Curr									
1Q	2.4A	4.4A	2.5E									
2Q	2.4A	10.1A	2.5E									
3Q	3.4A	3.3A	2.5E									
4Q	7.6A	4.5E	2.5E									
YEAR	15.7A	22.3E	10.0E									



ARCT: Bringing a STARR Vaccine to COVID-19

With global public health concerns around continued COVID-19 infection, ARCT announced a partnership (funded up to \$10M) early this morning with Duke-NUS (Singapore) to utilize its STARR technology for vaccine development. With STARR incorporating the essential elements of LUNAR mRNA design, we see a potential dataset in COVID-19 as an expedited shot on goal for validation of its mRNA platform.

Partnership with Duke-NUS puts ARCT at the forefront of COVID-19 knowledge, which can expedite development. Duke-NUS Medical School, an alliance between Duke SOM and the National University of Singapore, has been a central player in the struggle against COVID-19. With its deep study of the virus (Dr. Wang Linfa's team cultured the virus by Jan. 30) and pioneering work on two serum-based tests for infection, we see Duke-NUS as already far along the curve in understanding this novel coronavirus and how best ARCT can leverage its STARR technology to smartly and exepditiously design an mRNA-based vaccine. With a connection made through ARCT's board member Dr. Ed Holmes and his work in Singapore, the Singapore Economic Development Board (EDB) will provide up to \$10M to fund the COVID-19 vaccine effort and an opportunity to work with regulators to streamline the development program, which represents a significant boost forward in timeline for a key addition to ARCT's pipeline.

In our view, STARR's profile makes it ideally positioned as a response to infectious disease. First, let's recap the STARR (Self-Transcribing and Replicating RNA) platform: 1) Self-replicating RNA can given as a single solution with ARCT's proprietary LUNAR LNP, and has shown preclinical boosts of up to 30-fold vs. traditional mRNA vaccines; 2) LUNAR tech in STARR means that the quick clearing ATX lipids developed by ARCT are used to ensure a clean safety profile, which we see as especially vital given that these drugs will be tested and then administered in healthy patients; and 3) Duke-NUS is yet another partner for ARCT in the vaccine space, with a disclosed large pharma relationship for prophylactic vaccines, multiple animal health collaborations for ID vaccines, and a personalized cancer vaccine deal with Providence Therapeutics (potential entry into clinic late 2020/early 2021). With external validation of ARCT's vaccine capabilities coupled with STARR potentially necessitating smaller doses for COVID-19 vaccination from a company that has disclosed production of drug product at gram-scale quantities, we see increased shots on goal for ARCT's mRNA tech in an expanded set of indications beyond its central rare disease programs.

Intraday price: \$17.37 as of 10:09am ET

VALUATION

Our \$24/share price target is derived from a risk-adjusted net present value (rNPV) analysis, based on 1) \$8.00/share for LUNAR-OTC in the U.S. (launch 2023, 40% POS, \$554.6M peak sales); 2) \$10.00/share for LUNAR-OCT in the EU (launch 2023, 40% POS, \$501.7M peak sales); 3) \$3.00/share for LUNAR-CF in the U.S. (launch 2025, 30% POS, \$473.4M peak sales); and 4) \$3.00/share for LUNAR-CF in the EU (launch 2025, 30% POS, \$435.0M peak sales).

We have increased our PT to \$24 due to an increased confidence that ARCT will submit its IND for ARCT-810 in OTC by end of 1Q20 and receive acceptance, thus pushing up our POS (from 30% to 40%).

Specifically, we estimate \$1.1B peak sales for LUNAR-OTC in the U.S. and EU, based on the following assumptions: 1) There are approximately 5.7K and 7.4K patients with OTC deficiency in the U.S. and EU, respectively; 2) We estimate a 2023 launch in both markets, with an initial market penetration rate of 0.5-1% that will grow to 20% by 2028; 3) We model \$450K and \$315K initial annual costs of LUNAR-OTC in the U.S. and EU, respectively; and 4) We utilize a 11% discount rate.

We estimate \$908.4M peak sales for LUNAR-CF in the U.S. and EU, based on the following assumptions: 1) There are approximately 30K and 45K patients with CF in the U.S. and EU, respectively, of whom 80% are inadequately addressed with current treatments and seeking new options; 2) We estimate a 2025 launch in both markets, with an initial market penetration rate of 0.7-0.8% that will grow to 6-7% by 2028; 3) We model \$250K and \$175K initial annual costs of LUNAR-CF in the U.S. and EU, respectively; and 4) We utilize a 11% discount rate.

Impediments to our price target include clinical, financial, and regulatory risks.

As of September 30, 2019, ARCT reports cash and cash equivalents totaling \$74.2M.

RISKS

Clinical Risks. Success in early stage clinical trials does not guarantee success in later trials. ARCT-810 has never been tested in humans before, and ongoing and future studies may not be able to produce the necessary safety and efficacy profile for approval according to guided timelines. Arcturus only has preclinical pipeline candidates, some of which may never make it to human trials; too many failures of their candidates would have a large material impact on the company moving forward.

Company-related risks. Arcturus is an early-stage biopharmaceutical company that does not yet have any approved products. Thus, there is no revenue being generated so far, and the company will continue to incur losses for the foreseeable future. They currently have no product candidates in human clinical trials and no commercial sales. The company has also experienced some turbulence at the helm, with the Board voting to oust Joseph E. Payne and Dr. Chivukula stepping down in early 2018 before both were later reinstated to their previous positions in June. Additionally, the future successful commercialization and marketing of ARCT-810 is dependent on the company's ability to hire and train sales and marketing personnel, appropriate pricing structure of the drug, and sufficient implementation of drug distribution.

Regulatory risks. As we previously described, there are no currently approved therapies for management of OTC deficiency. Thus, Arcturus will be amongst the first to navigate the regulatory hurdles for this landscape, which may come with unexpected hurdles in trial design and clinical endpoints. It may also be the first to attempt to navigate it as a novel therapy class utilizing RNA. Arcturus may also incur additional costs or encounter unexpected delays in the development of ARCT-810, which may adversely affect the company.

COMPANY DESCRIPTION

Arcturus Therapeutics is a biopharmaceutical company from San Diego, CA, focused on the development of mRNA and other RNA modalities. The company has built a drug delivery platform called LUNAR, which stands for lipid enabled and unlocked nucleic acid RNA, and consists of lipid nanoparticles that are the backbone of its RNA lipid mediated delivery systems. LUNAR has provided Arcturus with a delivery method to target both the liver and lung, two important organs that are the home of several tough-to-treat diseases. Arcturus has two preclinical discovery programs, one in a rare liver disease called ornithine transcarbamylase deficiency (IND filing expected in 1Q20) and another in cystic fibrosis. The LUNAR program and mRNA therapy is perfectly suited to treat both of these disease, since the underlying cause is a protein mutation that is easily fixed by supplying new, wildtype protein. Arcturus Therapeutics' strong position as a leader in the RNA medicines space has been recognized in five collaborative pacts with pharma and biotech strategic partners.

Arcturus Therapeutics, Inc. (Nasdaq: ARCT)

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Income Statement

Year ended December 31	FY	FY	FY	2Q	FY	1Q	2Q	3Q	4Q	FY	1Q	2Q	3Q	4Q	FY	FY	FY	FY	FY	FY	FY	FY	FY
(In thousands of US\$)	2015A	2016A	2017A	March-18A	2018A	Mar-19A	Jun-19A	Sep-19A	Dec-19E	2019E	Mar-20E	Jun-20E	Sep-20E	Dec-20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
REVENUES																							1
LUNAR-CF - U.S.	-			-	-	-								-		-		-	-	47,588	124,172	259,205	473,44
LUNAR-CF - EU	-		-	-	-	-			-	-	-	-		-	-	-	-	-	-	43,721	114,083	238,145	434,98
Collaboration Revenue	6,138	20,382	12,998	2,367	15,753	4,350	10,153	3,318	4,500	22,321	2,500	2,500	2,500	2,500	10,000	25,000	12,500	12,500	15,000	20,000	25,000		1
Total Revenue	6,138	20,382	12,998	2,367	15,753	4,350	10,153	3,318	4,500	22,321	2,500	2,500	2,500	2,500	10,000	25,000	12,500	22,649	102,683	367,257	654,939	1,030,311	1,529,70
Operating expenses																							l
COGS	-		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2,038	8,215	29,381	52,395	82,425	122,37
Gross Profit	-	-	-	-	-	-	-	-	-	-			-	-	-	-	-	20,610	94,468	337,877	602,544	947,886	1,407,32
Research and development (R&D)	5,476	17,934	15,918	3,941	16,982	7,324	7,269	7,053	7,406	29,052	7,776	7,931	8,169	8,578	32,455	34,077	23,854	19,083	19,847	20,442	20,953	21,477	22,01
General and administrative (G&A)	2,574	3,448	7,572	5,098	20,582	3,534	3,456	3,881	4,075	14,946	4,157	3,949	4,028	4,149	16,282	18,724	20,596	21,626	22,707	23,615	24,560	25,297	25,92
Other (income) expenses	(11)	536	409			-				-								-			-		1
Total operating expense	8,039	21,918	23,899	9,039	37,564	10,858	10,725	10,934	11,481	43,998	11,932	11,880	12,197	12,726	48,736	52,801	44,450	42,748	50,768	73,438	97,908	129,199	170,32
Income (Loss) from operations	(1,901)	(1,536)	(10,901)	(6,672)	(21,811)	(6,508)	(572)	(7,616)	(6,981)	(21,677)	(9,432)	(9,380)	(9,697)	(10,226)	(38,736)	(27,801)	(31,950)	(20,099)	51,914	293,819	557,030	901,112	1,359,38
Loss related to equity method investment					(302)	(288)		303		15													1
Income tax expense	(1)	(35)	(1)	111	328	(88)	(113)	(120)	-	(321)				-		-		-	-	-		-	1
Pre-tax income (loss)	(1,902)	(1,571)	(10,902)	(6,561)	(21,785)	(6,884)	(685)	(7,433)	(6,981)	(21,983)	(9,432)	(9,380)	(9,697)	(10,226)	(38,736)	(27,801)	(31,950)	(20,099)	51,914	293,819	557,030	901,112	1,359,38
Provision for income taxes																				(50,201)	(178,250)	(288,356)	(435,00
Income tax rate	-			-	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	17.1%	32.0%	32.0%	32.0
N	(4.000)	(4.884)	(10.000)	(0.504)	(21.785)					(21,983)					(38,736)		(31.950)	(20.099)		243.618	378,781	612.756	924.38
Net income (Loss)	(1,902)	(1,571)	(10,902)	(6,561)	(21,785)	(6,884)	(685)	(7,433)	(6,981)	(21,983)	(9,432)	(9,380)	(9,697)	(10,226)	(38,736)	(27,801)	(31,950)	(20,099)	51,914	243,618	3/8,/81	612,756	924,38
Basic Shares Out	2,016	2,032	3,087	9,941	10,069	10,095	10,412	13,201	13,531	12,034	14,208	14,918	15,291	15,673	15,018	18,772	21,588	28,065	29,468	30,205	30,960	31,734	32,36
Diluted Shares Out	2,016	2,032	3,087	9,941	10,069	10,095	10,412	13,201	13,531	12,034	14,208	14,918	15,291	15,673	15,018	18,772	21,588	28,065	29,468	30,205	30,960	31,734	32,36
Basic EPS	(\$0.94)	(\$0.77)	(\$3.53)	(\$0.66)	(\$2.16)	(\$0.68)	(\$0.07)	(\$0.56)	(\$0.52)	(\$1.83)	(\$0.66)	(\$0.63)	(\$0.63)	(\$0.65)	(\$2.58)	(\$1.48)	(\$1.48)	(\$0.72)	\$1.76	\$8.07	\$12.23	\$19.31	\$28.5
Diluted EPS	(\$0.94)	(\$0.77)	(\$3,53)	(\$0.66)	(\$2,16)	(\$0.68)	(\$0.07)	(\$0,56)	(\$0.52)	(\$1.83)	(\$0,66)	(\$0.63)	(\$0.63)	(\$0.65)	(\$2,58)	(\$1,48)	(\$1,48)	(\$0.72)	\$1.76	\$8.07	\$12.23	\$19.31	\$28.5

Source: SEC filings and press releases; ROTH Capital Partners estimates

Consensus Estimates	2016A	2017E	March-18A	2018E	Mar-19A	Jun-19A	Sep-19A	Dec-19E	2019E	Mar-20E	Jun-20E	Sep-20E	Dec-20E	2020E	2021E
Revenue (\$M)								3.7	21.5	3.2	3.2	3.3	3.4	10.9	14.8
EPS - GAAP								(\$0.53)	(\$1.81)	(\$0.62)	(\$0.61)	(\$0.59)	(\$0.59)	(\$2.38)	(\$1.97)

Source: Thomson, March 4, 2020

Arcturus Therapeutics, Inc. (Nasdaq: ARCT)

ARCTURUS THERAPEUTICS HOLDINGS, INC.

Yasmeen Rahimi, Ph.D., ROTH Capital Partners <u>yrahimi@roth.com; (646) 616-2787</u>

Balance Sheet

Year ended December 31	FY	FY	2Q	3Q	4Q	FY	1Q	2Q	3Q
(In thousands of US\$)	2016A	2017A	Jun-18A	Sep-18A	Dec-18A	2018A	Mar-19A	Jun-19A	Sep-19A
ASSETS									
Current assets:									
Cash and cash equivalents	8,345	24.965	39,777	30,331	36,709	36,709	31,220	55,840	74,17
Restricted cash	-	166	-	-	-	-	-	-	
Short-term investments	-	23,608	_	2,499	-	-	-	-	
Accounts receivable	3,633	480	1,371	1,123	4,481	4,481	4,457	5,817	2,62
Prepaid expenses and other current assets	353	1,059	534	448	638	638	929	1,681	2,61
Intangible asset held for sale	-	590	-	-	-	-	-	-	
Total current assets	12,331	50,868	41,682	34,401	41,828	41,828	36,606	63,338	79,40
Property and equipment, net	1,335	1,049	-	2,064	1,975	1,975	2,016	1,986	2,07
Operating lease right-of-use asset	-	-	-	-	-	-	5,690	5,509	5,32
Equity method investment	-	-	-	543	288	288	-	-	30
Other assets	70	107	2,640	107	107	107	107	107	10
TOTAL ASSETS	13,736	52,024	44,322	37,115	44,198	44,198	44,419	70,940	87,21
LIABILITIES AND STOCKHOLDERS EQUITY									
Current liabilities:									
Accounts payable	3,357	1,790	2,781	2,905	2,398	2,398	4,118	3,187	4,01
Accrued expenses	1,061	2,793	2,701	2,244	3,907	3,907	2,766	3,497	6,67
Deferred revenue	4,183	6,457	_	8,451	6,272	6,272	7,728	9,730	10,99
Other current liabilities	.,	-	15,472	-	0,2.2	5,2.2	-,,,20	-	10,00
Notes payable - Insurance	133	-		_	-	-	-	_	
Total current liabilities	8,734	11,040	18,253	13,600	12,577	12,577	14,612	16,414	21,68
Deferred revenue, net current portion, other long term liabilitie	3,410	7.190	8,274	8,843	7,534	7,534	8,025	17.652	14,55
Long-term debt	-,		-,	-	9,911	9,911	9,945	9,980	10,01
Operating lease liability, net of current portion	_	_	_	_	-,	-,	5,483	5,276	5,06
Deferred rent	_	_	_	_	534	534	-	5,2.5	0,000
Other liabilities	_	_	_	521	-	-	_	_	
Total liabilities	12,144	18,230	26,527	22,964	30,556	30,556	38,065	49,322	51,32
Series seed preferred shares, \$0.0001 par value	_	_			_	_			
Series A preferred shares	_	-	_	_	_	_	-	_	
Ordinary shares	_	212	212	214	214	214	214	13	1
Additional paid-in capital	13,764	56,674	56,674	57,796	58,302	58,302	58,701	74,851	96,55
Accumulated other comprehensive loss	-,	(3)	-	4				,	,
Accumulated deficient	(12,187)	(23,089)	(39,091)	(43,863)	(44,874)	(44,874)	(52,561)	(53,246)	(60,67
Total stockholders' equity (deficit)	1,577	33,794	17,795	14,151	13,642	13,642	6,354	21,618	35,89
TOTAL LIABILITIES AND EQUITY	13,721	52.024	44,322	37.115	44,198	44,198	44,419	70.940	87,21

Source: SEC filings and press releases, ROTH Capital Partners estimates

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

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Within the last twelve months, ROTH has received compensation for non-investment banking securities-related services from Arcturus Therapeutics Holdings, Inc..



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

IB Serv./Past 12 Mos. as of 03/04/20

Rating	Count	Percent	Count	Percent
Buy [B]	263	76.68	151	57.41
Neutral [N]	43	12.54	20	46.51
Sell [S]	4	1.17	2	50.00
Under Review [UR]	33	9.62	15	45.45

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 stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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