

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 8, 2019**

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**AVADEL PHARMACEUTICALS PLC**  
(Exact name of registrant as specified in its charter)

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**Ireland**  
(State or Other Jurisdiction  
of Incorporation)

**001-37977**  
(Commission File Number)

**98-1341933**  
(I.R.S. Employer  
Identification No.)

**Block 10-1**  
**Blanchardstown Corporate Park, Ballycoolin**  
**Dublin 15, Ireland**  
(Address of Principal Executive Offices)

**Not Applicable**  
(Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 8, 2019, Avadel Pharmaceuticals plc (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2019. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1	<a href="#">Press release dated May 8, 2019, issued by Avadel Pharmaceuticals plc*</a>
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\* This information shall be deemed to be "furnished" and not filed herewith.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AVADEL PHARMACEUTICALS PLC**

By: /s/ Michael F. Kanan  
Michael F. Kanan  
Senior Vice President, Chief  
Financial Officer

Date: May 8, 2019

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Exhibit Index

99.1	<a href="#">Press release dated May 8, 2019, issued by Avadel Pharmaceuticals plc*</a>
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\* This information shall be deemed to be "furnished" and not filed herewith.



## Avadel Pharmaceuticals Reports First Quarter 2019 Financial Results

- *REST-ON 63% enrolled; 98 patients remain to be enrolled*
- *Jordon Dubow, M.D., appointed as Chief Medical Officer*
- *Noctiva™-related assets sold; all operational activities have ceased*

DUBLIN, Ireland, May 8, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for sleep disorders, today announced its financial results for the first quarter of 2019 and provided an update on its transformational progress.

"We have made substantial progress on restructuring the company, since our announcement in February to make development of FT218 the core focus of the company," said Greg Divis, Interim Chief Executive Officer. "FT218 is a novel, once nightly therapy being studied for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. In keeping with our commitment to deliver on the promise of FT218, we recently hired Jordon Dubow, M.D., as our Chief Medical Officer. Dr. Dubow brings many years of relevant neurology experience, including in sleep, to Avadel and his insight will be invaluable as we continue to advance FT218."

Dr. Dubow added, "Having had the opportunity to review findings from the third-party diagnostic of the REST-ON clinical trial and the FT218 development program more broadly, I am confident in the status of the program overall and in our ability to complete trial enrollment in the second half of 2020. I believe that FT218 is a highly promising product candidate with clear differentiation over standard-of-care in a large addressable market and could provide significant clinical benefit to patients suffering from narcolepsy."

### First quarter and recent company highlights

- The REST-ON clinical trial has enrolled 166 patients, which is 63% of the target enrollment; 98 patients remain to be enrolled; based on current trends, enrollment is expected to be completed in the second half of 2020;
  - The Company has been issued new intellectual property covering FT218's novel once nightly formulation; the patent issued from the U.S. Patent and Trademark Office has an expiry date in 2037;•
  - Jordan Dubow, M.D., was appointed Chief Medical Officer; Dr. Dubow will lead the development of FT218;
  - The assets of Avadel Specialty Pharmaceuticals, LLC, a subsidiary solely responsible for the sales, marketing and distribution of Noctiva™, have been sold; there are no Noctiva-related personnel or activities remaining at the Company;
  - Restructuring actions already completed will result in \$50 to \$60 million of annual cost savings; actions underway, and expected to conclude before December 31, 2019, are expected to realize the full \$80-\$90 million of cost reductions previously announced; and
  - Revenues of \$16.4 million in the first quarter of 2019 exceeded the top of end of the Company's previous guidance of \$13 to \$15 million; annual revenue is now expected to exceed \$30 million (vs. the prior expectation of annual revenue possibly below \$30 million).
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## Overview of first quarter 2019 financial results:

Revenues for the first quarter of 2019 were \$16.4 million, compared to \$33.3 million in the first quarter of 2018. The decline on a year-over-year basis was primarily attributed to lower net selling prices across all of the Company's hospital products as a result of increased market competition. Revenue for the first quarter of 2019 exceeded the top end of the guided range provided in March of \$13 to \$15 million.

Revenues by Product: (\$ in 000s)	Three Months Ended March 31,	
	2019	2018
Bloxiverz	\$ 2,568	\$ 7,491
Vazculep	9,473	12,961
Akovaz	3,792	10,217
Other (1)	604	2,492
Total product sales	<u>16,437</u>	<u>33,161</u>
License revenue	-	132
Total revenues	<u>\$ 16,437</u>	<u>\$ 33,293</u>

(1) Noctiva revenue included in "Other"; Noctiva revenue for the three months ended March 31, 2019 represents revenue earned from January 1, 2019 through February 5, 2019, prior to the deconsolidation of Avadel Specialty Pharmaceuticals, LLC.

Research and development (R&D) expense was \$7.3 million in the first quarter of 2019 compared to \$10.0 million in the first quarter of 2018. This decline was a result of \$1.3 million of lower spending associated with the exit of Noctiva and \$1.2 million of cost reductions at the company's Lyon, France R&D center. The company continues to invest a substantial portion of R&D in its FT218 development program.

Selling, general and administrative (SG&A) expense was \$10.4 million in the first quarter of 2019 compared to \$24.5 million for the first quarter of 2018. This decrease is a result of a decline in sales and marketing costs of \$10.1 million associated with exit of Noctiva and costs of \$2.7 million in the first quarter of 2018 that did not recur in the first quarter of 2019 due to the February 2018 disposition of the company's pediatric products.

Net loss for the first quarter of 2019 was \$13.0 million or \$0.35 per share compared to a net loss of \$12.2 million or \$0.32 per share for the same period in 2018. Included in the net loss in the first quarter of 2019 was a loss on the deconsolidation of Avadel Specialty Pharmaceuticals, LLC of \$2.7 million. As a result of Avadel Specialty Pharmaceuticals, LLC bankruptcy filing on February 6, 2019, the company concluded that it no longer controls the operations of this subsidiary and accordingly deconsolidated this subsidiary.

Cash, cash equivalents and marketable securities were \$79.9 million as of March 31, 2019, compared to \$99.9 million as of December 31, 2018. Based on our current FT218 clinical development plan, anticipated cost structure and hospital products revenue projections, cash is anticipated to be sufficient to fund operations into 2021. The company has convertible debt of \$144 million due in 2023.

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## **2019 Guidance:**

Based on recent hospital products sales performance and continuing to factor in increased competition from products launched, expected to be launched in 2019, and possible market price actions, which have not yet occurred, hospital product revenue for 2019 is now expected to exceed \$30 million. The Company submitted an NDA to the U.S. Food and Drug Administration (FDA) in March of 2019 on a fourth Hospital Product, AV001, which, if approved, could contribute revenues to Avadel in 2020.

## **Conference Call:**

A conference call to discuss these results has been scheduled for Wednesday, May 8, 2019 at 8:30 a.m. EDT. A question and answer period will follow management's prepared remarks. To access the conference call, investors are invited to dial (844) 388-0559 (U.S. and Canada) or (216) 562-0393 (International). The conference ID number is 3258059. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, [www.avadel.com](http://www.avadel.com). A replay of the webcast will be archived on Avadel's website for 90 days following the event.

## **About Avadel Pharmaceuticals plc:**

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. The Company's primary focus is on the development and potential FDA approval for FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel markets three sterile injectable drugs used in the hospital setting, which were developed under the Company's "unapproved marketed drug" (UMD) program. Avadel is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit [www.avadel.com](http://www.avadel.com).

## **Cautionary Disclosure Regarding Forward-Looking Statements**

This press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "guidance," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof (if applicable).

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in our forward-looking statements include:

(a) risks relating to our 2018 net loss and recent restructuring plan, including risks relating to the following:

- due to a decrease in our available liquid assets, our business strategy has been refocused and is now substantially dependent upon a single product, FT218;
  - our recent restructuring plan may not be as effective as we anticipate and may have unintended negative impacts;
  - further restructuring actions, if needed, may require third-party consents that may not be granted;
  - the Chapter 11 bankruptcy filing by our subsidiary Avadel Specialty Pharmaceuticals LLC may have unexpected adverse results; and
  - a management-directed third-party evaluation of our FT218 development program could result in changes that increase the cost of the program and further delay its completion;
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(b) risks relating to the following:

- our three products Bloxiverz®, Vazculep® and Akovaz®, which are not patent protected, and have a small number of customers, produce a majority of our revenues, and could face further competition resulting in a further loss of market share and/or forcing us to further reduce our prices for those products;
- our current "unapproved marketed drug" (UMD) product candidate, AV001, could fail to achieve FDA approval; or we could fail to develop future potential UMD product candidates, or competitors could develop such products and market such products with FDA approval before us;
- we could experience failure or further delay in completing the Phase III clinical trial for FT218, and if the FDA ultimately approves such product, the approval may not include any period of market exclusivity;
- we may not have sufficient cash or the ability to raise sufficient cash to service our \$143.75 million Exchangeable Senior Notes due 2023, including cash necessary to repay such Notes at maturity, to settle exchanges of such Notes in cash or to repurchase such Notes as required following a "fundamental change" event described in the indenture governing such Notes;
- our products may not reach the commercial market or gain market acceptance;
- we must invest substantial sums in research and development in order to remain competitive;
- we depend on one or a limited number of providers to develop certain of our products and drug delivery technologies, to manufacture certain of our products and to provide certain raw materials used in our products;
- our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do;
- we face challenges in protecting intellectual property underlying our products and drug delivery technologies; and
- we depend on key personnel to execute our business plan.

(c) the other risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise the forward-looking statements contained in this Annual Report.

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**Burns McClellan**

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**AVADEL PHARMACEUTICALS PLC**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS**

*(In thousands, except per share data)*

*(Unaudited)*

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenues:		
Product sales	\$ 16,437	\$ 33,161
License revenue	—	132
Total revenues	16,437	33,293
Operating expenses:		
Cost of products	3,266	6,592
Research and development expenses	7,329	9,951
Selling, general and administrative expenses	10,446	24,487
Intangible asset amortization	201	1,767
Gain - changes in fair value of related party contingent consideration	2,134	2,968
Restructuring costs	1,228	153
Total operating expenses	24,604	45,918
Operating loss	(8,167)	(12,625)
Investment and other income, net	817	54
Interest expense	(3,062)	(1,597)
Loss on deconsolidation of subsidiary	(2,673)	—
Other income - changes in fair value of related party payable	(307)	(395)
Loss before income taxes	(13,392)	(14,563)
Income tax benefit	(374)	(2,327)
Net loss	\$ (13,018)	\$ (12,236)
Net loss per share - basic	\$ (0.35)	\$ (0.32)
Net loss per share - diluted	(0.35)	(0.32)
Weighted average number of shares outstanding - basic	37,354	38,559
Weighted average number of shares outstanding - diluted	37,354	38,559



**AVADEL PHARMACEUTICALS PLC**  
**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**

*(In thousands, except per share data)*

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
	<i>(unaudited)</i>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,630	\$ 9,325
Marketable securities	70,221	90,590
Accounts receivable	11,772	11,330
Inventories	4,258	4,770
Prepaid expenses and other current assets	6,556	8,836
Total current assets	102,437	124,851
Property and equipment, net	1,749	1,911
Operating lease right-of-use assets	5,802	—
Goodwill	18,491	18,491
Intangible assets, net	1,428	1,629
Research and development tax credit receivable	7,591	7,272
Other non-current assets	36,124	36,146
Total assets	\$ 173,622	\$ 190,300
<b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 104	\$ 106
Current portion of long-term related party payable	9,391	9,439
Current portion of operating lease liability	982	—
Accounts payable	4,150	3,503
Deferred revenue	115	114
Accrued expenses	14,689	21,695
Other current liabilities	1,927	3,526
Total current liabilities	31,358	38,383
Long-term debt, less current portion	117,178	115,734
Long-term related party payable, less current portion	18,202	19,401
Long-term operating lease liability	3,889	—
Other non-current liabilities	12,577	14,002
Total liabilities	183,204	187,520
Shareholders' (deficit) equity:		
Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; none issued or outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 42,762 issued and 37,355 outstanding at March 31, 2019 and 42,720 issued and 37,313 outstanding at December 31, 2018	427	427
Treasury shares, at cost, 5,407 shares held at March 31, 2019 and December 31, 2018, respectively	(49,998)	(49,998)
Additional paid-in capital	434,199	433,756
Accumulated deficit	(371,007)	(357,989)
Accumulated other comprehensive loss	(23,203)	(23,416)
Total shareholders' (deficit) equity	(9,582)	2,780
Total liabilities and shareholders' (deficit) equity	\$ 173,622	\$ 190,300



AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands, Unaudited)

	Three Months Ended March 31,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (13,018)	\$ (12,236)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	369	1,985
Amortization of premiums on marketable securities	9	518
Remeasurement of related party acquisition-related contingent consideration	2,134	2,968
Remeasurement of related party financing-related contingent consideration	307	395
Amortization of debt discount and debt issuance costs	1,445	657
Change in deferred tax and income tax deferred charge	(222)	(2,851)
Stock-based compensation expense	351	2,134
Loss on deconsolidation of subsidiary	1,750	—
Other adjustments	(550)	139
Net changes in assets and liabilities		
Accounts receivable	(1,021)	(1,891)
Inventories	467	(466)
Prepaid expenses and other current assets	(3,228)	(2,285)
Research and development tax credit receivable	(449)	(494)
Accounts payable & other current liabilities	752	6,374
Accrued expenses	(4,750)	(5,854)
Accrued income taxes	(46)	32
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(3,181)	(5,790)
Royalty payments for related party payable in excess of original fair value	(507)	(825)
Other assets and liabilities	(1,818)	(518)
Net cash used in operating activities	<u>(21,206)</u>	<u>(18,008)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(30)	(41)
Proceeds from sales of marketable securities	34,864	194,400
Purchases of marketable securities	<u>(13,444)</u>	<u>(275,098)</u>
Net cash provided by (used in) investing activities	<u>21,390</u>	<u>(80,739)</u>
<b>Cash flows from financing activities:</b>		
Earn-out payments for related party contingent consideration	—	(402)
Proceeds from debt issuance	—	143,750
Payments for debt issuance costs	—	(5,391)
Share repurchases	—	(18,000)
Proceeds from the exercise of warrants	—	2,911
Other financing activities, net	92	47
Net cash provided by financing activities	<u>92</u>	<u>122,915</u>
Effect of foreign currency exchange rate changes on cash and cash equivalents	29	179
Net change in cash and cash equivalents	305	24,347
Cash and cash equivalents at January 1,	9,325	16,564
Cash and cash equivalents at March 31,	<u>\$ 9,630</u>	<u>\$ 40,911</u>

