# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

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

Date of Report (Date of earliest event reported): November 5, 2018

# AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland

**000-28508** (Commission File Number) **98-1341933** (I.R.S. Employer Identification No.)

(State or Other Jurisdiction of Incorporation)

> 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

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

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

On November 5, 2018, Avadel Pharmaceuticals plc (the "Company") issued a press release announcing its earnings for the quarter ended September 30, 2018. That press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information responsive to this Item 2.02 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 (the "Securities Act") or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

#### Item 7.01 Regulation FD Disclosure.

On November 5, 2018, the Company posted to its website a set of presentation materials that it will use during its earnings call and webcast to assist participants with understanding the Company's financial results for the quarter ended September 30, 2018. A copy of this presentation is attached hereto as Exhibit 99.2.

The information responsive to this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated November 5, 2018, issued by Avadel Pharmaceuticals plc \*

99.2 Presentation materials dated November 5, 2018, issued by Avadel Pharmaceuticals plc\*

\* This information shall be deemed to be "furnished" and not filed herewith.

#### 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/ Phillandas T. Thompson

Phillandas T. Thompson Senior Vice President, General Counsel and Corporate Secretary

Date: November 5, 2018

#### **Exhibit Index**

99.1 Press release dated November 5, 2018, issued by Avadel Pharmaceuticals plc \*

99.2 Presentation materials dated November 5, 2018, issued by Avadel Pharmaceuticals plc\*

\* This information shall be deemed to be "furnished" and not filed herewith.



# **Avadel Pharmaceuticals Reports Third Quarter 2018 Financial Results**

**Dublin, Ireland - November 5, 2018 -** Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on providing innovative medicines for chronic urological, central nervous system, and sleep disorders, today announced its financial results for the third quarter of 2018.

Mike Anderson, Avadel's Chief Executive Officer, said, "We executed a number of important initiatives during the third quarter related to our REST-ON Phase 3 FT 218 clinical study in narcolepsy and our recently launched product, NOCTIVA<sup>TM</sup>. For REST-ON, we completed 10 new clinical site initiations, hosted two successful patient events with well over 100 attendees, and recently launched a patient referral program in tandem with a new ad campaign, all of which have opened us up to new pools of potential patients."

"While prescription uptake for NOCTIVA is a bit slower than we anticipated, a number of important metrics have continued to improve over the last 3 months. We have substantially grown our prescriber base and have seen triple the number of prescriptions since the start of August, resulting in almost 8,000 dispensed prescriptions to date from over 1,800 unique prescribers. Our unaided brand awareness increased to approximately 80 percent, up from just under 60 percent in August, and recent intent-to-treat data indicates that 85 percent of targeted physicians expect to increase use of NOCTIVA in the next 6 months. Although the level of financial assistance to ensure patient access continues to impact revenue, we improved coverage through commercial insurance plans during the quarter and now have almost 140 million lives with access to NOCTIVA. In addition, we secured our first Part D contract with a top 5 provider and believe as we further expand access and drive demand we will improve our top line results."

#### **Overview of third quarter 2018 financial results:**

#### **Revenues by product:** Three Months Ended September 30, 2018 (\$ in 000s) 2017 \$ Bloxiverz 3,656 \$ 9,920 Vazculep 8,759 9,573 Akovaz 5,991 18,561 Noctiva 1,047 Other 373 1,093 19,826 39,147 Product sales License revenue 528 Total revenues \$ 19,826 \$ 39,675

Revenues for the third quarter 2018 were \$19.8 million, compared to \$39.7 million in the third quarter 2017. The decline on a year-over-year basis was attributed to lower net selling prices across all of our hospital products and lower unit volumes for Akovaz® and Bloxiverz® as a result of increased market competition. Net sales for NOCTIVA, which was launched in May 2018, were \$1.0 million in the third quarter 2018, up from \$0.3 million in the second quarter 2018.

<sup>&</sup>lt;sup>(1)</sup> Descriptions of Avadel's non-GAAP financial measures are included under the caption Non-GAAP Disclosures and Adjustments included within this press release and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the Supplemental Information section herein.

#### **Operating expenses:**

	Т	Three Months Ended September 30,									
(\$ in 000s)		2018		2017							
Cost of products	\$	3,120	\$	3,790							
Research and development expenses (R&D)		11,402		8,095							
Selling, general and administrative expenses (SG&A)		24,829		11,563							

R&D expense was up \$3.3 million in the third quarter 2018 compared to the prior year period, primarily due to increased spend on the Phase 3 REST-ON trial. The \$13.3 million increase in SG&A in the third quarter 2018 compared to the third quarter 2017 was due to sales and marketing expenses associated with the May 2018 launch of NOCTIVA.

#### GAAP earnings (loss):

	Three	Three Months Ended September 30,									
(\$ in 000s except for per share)	20	18		2017							
Net (loss) income	\$	(15,771)	\$	21,679							
Net (loss) income per share - diluted		(0.43)		0.52							

Included in GAAP net loss for the third quarter 2018 were gains of \$7.1 million related to changes in the fair value of related party contingent consideration, compared to gains of \$9.9 million in the same period last year. These non-cash gains were recorded as a result of reducing the fair value of related party contingent consideration due to changing market conditions across the Company's three hospital products. Additionally, included in GAAP net loss for the third quarter 2018 was \$3.0 in interest expense related to the Company's convertible notes issued in February 2018.

Adjusted earnings (loss) <sup>(1)</sup> :	Th	Three Months Ended September 30,									
(\$ in 000s except for per share)		2018									
Adjusted net (loss) income	\$	(23,969)	\$	3,747							
Adjusted net (loss) income per share - diluted		(0.65)		0.09							

The decrease in adjusted net income is largely attributable to lower revenues from the Company's hospital products, higher SG&A due to the 2018 launch of NOCTIVA and increased R&D spend on the Phase 3 REST-ON trial. Please see the Supplemental Information section within this document for a reconciliation of adjusted net income and adjusted diluted EPS to the respective GAAP amounts.

#### 2018 Guidance:

The Company is maintaining its full-year 2018 revenue guidance of \$90 to \$105 million, and its full-year R&D spend guidance of \$40 to \$50 million. SG&A is now expected to range between \$85 to \$95 million for the full year compared to \$80 to \$90 million in our previous guidance. Within the 2018 revenue guidance, the Company does not anticipate reaching the low end of its previous guidance for NOCTIVA of \$5 million, due to a higher mix of Medicare Part D scripts, high levels of copay assistance, and lower overall script growth compared to the assumptions used for such previous guidance. Cash interest expense paid and accrued on the Company's convertible notes issued in February 2018 is expected to be approximately \$6 million, and a non-GAAP tax benefit of 0% to 10% of loss before tax is anticipated for the full year 2018.

#### **Conference Call:**

<sup>(1)</sup> Descriptions of Avadel's non-GAAP financial measures are included under the caption Non-GAAP Disclosures and Adjustments included within this press release and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the Supplemental Information section herein.

A conference call to discuss these results has been scheduled for Monday, November 5, 2018 at 10:00 a.m. EST. 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 6799356. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, 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 specialty pharmaceutical company that seeks to develop differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, by utilizing its proprietary drug delivery technology and through in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. Avadel's current portfolio of products and product candidates focuses on the urology, central nervous system (CNS) / sleep, and hospital markets. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: This press release may include 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. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project," "guidance" and similar expressions, and (as applicable) the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on estimates and assumptions made within the bounds of our knowledge of our business and operations, 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. These risks include: (i) risks relating to our exchangeable senior notes including use of the net proceeds from the offering of the notes and other future events related to the notes; (ii) risks relating to the divestiture of our former pediatric business including whether such divestiture will be accretive to our operating income and cash flow; (iii) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including that a potential competitive product, and patent litigation with the manufacturer of that product, could have a material adverse impact on our ability to successfully exploit any market opportunity for the drug desmopressin acetate (the "Drug") which we are marketing under the brand name NOCTIVA<sup>tm</sup>, our internal analyses may overstate the market opportunity in the United States for the Drug or we may not effectively exploit such market opportunity, that significant safety or drug interaction problems could arise with respect to the Drug, that we may not successfully increase awareness of nocturia and the potential benefits of the Drug, and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (iv) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2017, in particular disclosures therein that may be set forth under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz<sup>®</sup>, Vazculep<sup>®</sup> and Akovaz<sup>®</sup> products, which are not patent protected, could continue to face substantial and increased competition resulting in a loss of market share and/or forcing us to further reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; the possibility that we could experience failure or delay in completing the Phase 3 clinical trial for our "FT 218" sodium oxybate product known as REST-ON); the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that 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; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; and our dependence on key personnel to execute our business plan. Forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by us and our management, are

<sup>(1)</sup> Descriptions of Avadel's non-GAAP financial measures are included under the caption Non-GAAP Disclosures and Adjustments included within this press release and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the Supplemental Information section herein.

inherently uncertain. Accordingly, you should not place undue reliance on forward-looking statements, which speak only as of the date they are made, and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.

#### **Non-GAAP Disclosures and Adjustments**

In addition to reporting its financial results in accordance with generally accepted accounting principles in the U.S.("GAAP"), Avadel discloses certain non-GAAP financial measures, including adjusted net income and loss and adjusted net income and loss per diluted share, as management believes that such non-GAAP financial measures can enhance an overall understanding of the Company's financial performance when considered together with financial measures prepared in accordance with GAAP. The non-GAAP results disclosed herein (a) exclude, in each case to the extent applicable, fair value remeasurements of its contingent consideration, amortization of debt discount and debt issuance costs attributable to our exchangeable notes, impairment of intangible assets, amortization of intangible assets, foreign exchange gains and losses on assets and liabilities denominated in foreign currencies, unrealized gains/losses on marketable equity securities, but (b) include the cash payments plus any unpaid accrued cash payments associated with the contingent consideration and cash interest payments or related accruals on the exchangeable notes. Our management uses these non-GAAP measures internally for forecasting, budgeting and measuring the Company's operating performance. Investors and other readers should review the related GAAP financial measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. The table provided within the following "Supplemental Information" section reconciles GAAP net income and loss and other earnings or loss per share to the corresponding adjusted (i.e., "non-GAAP") amounts.

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#### **Contacts:**

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Lauren Stival

**Sr. Director, Investor Relations & Corporate Communications** Phone: (636) 449-5866 Email: lstival@avadel.com

<sup>(1)</sup> Descriptions of Avadel's non-GAAP financial measures are included under the caption Non-GAAP Disclosures and Adjustments included within this press release and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the Supplemental Information section herein.



# AVADEL PHARMACEUTICALS PLC

# UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(In thousands, except per share data)

	1	Three Months En	ded S	eptember 30,		Nine Months End	September 30,	
		2018		2017	2018			2017
Revenues:								
Product sales	\$	19,826	\$	39,147	\$	82,103	\$	138,009
License revenue		_		528		246		484
Total revenues		19,826		39,675		82,349		138,493
Operating expenses:								
Cost of products		3,120		3,790		13,224		12,253
Research and development expenses		11,402		8,095		33,243		22,093
Selling, general and administrative expenses		24,829		11,563		77,159		35,804
Intangible asset amortization		1,620		564		4,996		1,692
Gain - changes in fair value of related party contingent consideration		(7,115)		(9,906)		(17,036)		(30,107)
Restructuring costs		65		(549)		268		3,173
Total operating expenses		33,921		13,557		111,854		44,908
Operating (loss) income		(14,095)		26,118		(29,505)		93,585
Investment and other income, net		208		977		845		2,562
Interest expense		(3,000)		(263)		(7,577)		(789)
Other income - changes in fair value of related party payable		425		768		1,432		2,988
(Loss) income before income taxes		(16,462)		27,600		(34,805)		98,346
Income tax (benefit) provision		(691)		5,921		(3,360)		21,830
Net (loss) income	\$	(15,771)	\$	21,679	\$	(31,445)	\$	76,516
Net (loss) income per share - basic	\$	(0.43)	\$	0.54	\$	(0.84)	\$	1.87
		(0.43)	φ	0.54	ф	(0.84)	φ	1.81
Net (loss) income per share - diluted		(0.45)		0.52		(0.04)		1.01
Weighted average number of shares outstanding - basic		36,904		40,061		37,410		40,839
Weighted average number of shares outstanding - diluted		36,904		41,339		37,410		42,194



## AVADEL PHARMACEUTICALS PLC UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	Septem	ber 30, 2018	December 31, 2017			
ASSETS						
Current assets:						
Cash and cash equivalents	\$	17,837	\$	16,564		
Marketable securities		107,425		77,511		
Accounts receivable		9,725		14,785		
Inventories		6,030		6,157		
Prepaid expenses and other current assets		6,859		8,958		
Total current assets	-	147,876	-	123,975		
Property and equipment, net		2,288		3,001		
Goodwill		18,491		18,491		
Intangible assets, net		69,339		92,289		
Research and development tax credit receivable		6,168		5,272		
Other non-current assets		24,844		10,249		
Total assets	\$	269,006	\$	253,277		
LIABILITIES AND SHAREHOLDERS' EQUITY						
Current liabilities:						
Current portion of long-term debt	\$	107	\$	111		
Current portion of long-term related party payable	Ψ	10,979	Ψ	25,007		
Accounts payable		11,399		7,477		
Deferred revenue		1,720		2,007		
Accrued expenses		20,698		50,926		
Other current liabilities		20,030		1,011		
Total current liabilities	-	47,019	-	86,539		
Long-term debt, less current portion		114,382		156		
Long-term related party payable, less current portion		27,713		73,918		
Other non-current liabilities		14,150		7,084		
Total liabilities		203,264		167,697		
		203,204		107,097		
Shareholders' equity:						
Preferred shares, \$0.01 nominal value; 50,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; none issued or outstanding at September 30, 2018 and December 31, 2017, respectively		_		_		
Ordinary shares, nominal value of \$0.01; 500,000 shares authorized; 42,420 issued and 37,012 outstanding at September 30, 2018 and 41,463 issued and 39,346 outstanding at December 31, 2017		424		414		
Treasury shares, at cost, 5,408 and 2,117 shares held at September 30, 2018 and December 31, 2017, respectively		(49,998)		(22,361)		
Additional paid-in capital		433,097		393,478		
Accumulated deficit		(294,130)		(262,685)		
Accumulated other comprehensive loss		(23,651)		(23,266)		
Total shareholders' equity		65,742		85,580		
Total liabilities and shareholders' equity	\$	269,006	\$	253,277		



### AVADEL PHARMACEUTICALS PLC UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	 Nine months end	ed Sept	ember 30,
	 2018		2017
Cash flows from operating activities:			
Net (loss) income	\$ (31,445)	\$	76,516
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	5,625		2,664
Amortization of premiums on marketable securities	2,889		653
Remeasurement of related party acquisition-related contingent consideration	(17,036)		(30,107
Remeasurement of related party financing-related contingent consideration	(1,432)		(2,988
Amortization of debt discount and debt issuance costs	3,402		_
Change in deferred tax and income tax deferred charge	(4,675)		322
Stock-based compensation expense	7,190		6,019
Other adjustments	117		(1,076
Net changes in assets and liabilities			
Accounts receivable	5,059		(6,240
Inventories	(548)		(2,612
Prepaid expenses and other current assets	2,194		1,924
Research and development tax credit receivable	(1,350)		(1,57
Accounts payable & other current liabilities	4,312		804
Accrued expenses	(11,660)		9,324
Accrued income taxes	(228)		5,820
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(16,254)		(24,72
Royalty payments for related party payable in excess of original fair value	(2,362)		(3,44
Other assets and liabilities	(1,988)		(80
Net cash (used in) provided by operating activities	 (58,190)		30,478
Cash flows from investing activities:			
Purchases of property and equipment	(167)		(533
Purchase of intangible asset	(20,000)		(52,139
Proceeds from sales of marketable securities	308,015		153,398
Purchases of marketable securities	 (341,036)		(115,893
Net cash used in investing activities	 (53,188)		(15,16)
Cash flows from financing activities:			
Earn-out payments for related party contingent consideration	(645)		(963
Proceeds from debt issuance	143,750		_
Payments for debt issuance costs	(6,190)		_
Share repurchases	(27,637)		(16,70)
Proceeds from the issuance of ordinary shares and warrants	3,488		370
Other financing activities, net	 (31)		_
Net cash provided by (used in) financing activities	 112,735		(17,292
Effect of foreign currency exchange rate changes on cash and cash equivalents	(84)		215
Net change in cash and cash equivalents	1,273		(1,76
Cash and cash equivalents at January 1,	16,564		39,215
Cash and cash equivalents at September 30,	\$ 17,837	\$	37,449



# AVADEL PHARMACEUTICALS PLC UNAUDITED SUPPLEMENTAL INFORMATION

(In thousands, except per share data)

Th	ree Months Er	nded Se	ptember 30,	Nine Months Ended September 30,					
	2018		2017	2018			2017		
\$	3,656	\$	9,920	\$	16,691	\$	37,541		
	8,759		9,573		33,097		29,906		
	5,991		18,561		28,083		65,110		
	1,047		_		2,002		_		
	373		1,093		2,230		5,452		
	19,826		39,147		82,103		138,009		
	_		528		246		484		
\$	19,826	\$	\$ 39,675		\$ 82,349		138,493		
		2018 \$3,656 8,759 5,991 1,047 373 19,826 —	2018   \$ 3,656 \$   8,759 5,991   1,047 373   19,826 —	\$   3,656   \$   9,920     8,759   9,573     5,991   18,561     1,047      373   1,093     19,826   39,147      528	2018     2017       \$ 3,656     \$ 9,920     \$       8,759     9,573     5       1,047      373     1,093       19,826     39,147      528	2018     2017     2018       \$ 3,656     \$ 9,920     \$ 16,691       \$ 3,656     \$ 9,920     \$ 16,691       8,759     9,573     33,097       5,991     18,561     28,083       1,047     —     2,002       373     1,093     2,230       19,826     39,147     82,103       —     528     246	2018     2017     2018       \$ 3,656     \$ 9,920     \$ 16,691     \$       \$ 3,656     \$ 9,920     \$ 16,691     \$       \$ 8,759     9,573     33,097     \$       \$ 5,991     18,561     28,083     \$       \$ 1,047      2,002     \$       \$ 19,826     39,147     82,103     \$       \$ 2018      528     246     \$		



			GAAP to N	lon-GAAP adjustn	nents for the three	e-months ended S	September 30, 2018			
					Exclude			Include		
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Equity securities unrealized (gain)/loss impact	Amortization of debt discount and debt issuance costs	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP
Revenues:										
Product sales	\$ 19,826	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ _	\$	\$ 19,826
License revenue										
Total revenues	19,826	_	_	_	_	_	_	_	_	19,826
Operating expenses:										
Cost of products	3,120	_	—	_	_	_	_	_	_	3,120
Research and development expenses	11,402	_	_	_	_	_	_	_	_	11,402
Selling, general and administrative expenses	24,829	_	_	_			_	_	_	24,829
Intangible asset amortization	1,620	(1,620)							(1,620)	,
Gain - changes in fair value of related party contingent consideration	(7,115)	(1,020)	_	_	_		7,115	3,182	(1,620)	3,182
	(7,113)	_	_	(65)		_	7,115	5,102		3,102
Restructuring costs Total operating				(65)					(65)	
expenses	33,921	(1,620)		(65)			7,115	3,182	8,612	42,533
Operating (loss) income	(14,095)	1,620	—	65	—	—	(7,115)	(3,182)	(8,612)	(22,707)
Investment and other income, net	208	_	7	_	(53)	_	_	_	(46)	162
Interest expense	(3,000)	—	—		—	1,383	—	—	1,383	(1,617)
Other income - changes in fair value of related party payable	425	_	_	_			(425)	(484)	(909)	(484)
(Loss) income before income taxes	(16,462)	1,620	7	65	(53)	1,383	(7,540)	(3,666)	(8,184)	(24,646)
Income tax (benefit) provision	(691)	341	_	_	4	_	(186)	(145)	14	(677)
Net (loss) income	\$ (15,771)	\$ 1,279	\$ 7	\$ 65	\$ (57)	\$ 1,383	\$ (7,354)	\$ (3,521)	\$ (8,198)	\$(23,969)
Net income (loss) per share - diluted <sup>(1)</sup>	\$ (0.43)	\$ 0.03	\$	\$ —	\$ —	\$ 0.04	\$ (0.20)	\$ (0.10)	\$ (0.22)	\$ (0.65)
Weighted average number of shares outstanding - diluted	36,904	36,904	36,904	36,904	36,904	36,904	36,904	36,904	36,904	36,904

(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full precision.



		GAAP to Nor	-GAAP adjust	ments for the thr	ee-months ended Se	ptember 30, 2017		
				Exclude		Include		
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP
Revenues:								
Product sales	\$ 39,147	\$ —	\$ —	\$ —	\$ —	\$ —	\$	\$ 39,147
License revenue	528							528
Total revenues	39,675	_	_	_	_	_	_	39,675
Operating expenses:								
Cost of products	3,790	_	_	_	_	_	_	3,790
Research and development expenses	8,095	_	_	_	—		—	8,095
Selling, general and administrative expenses	11,563	_	_	_				11,563
Intangible asset amortization	564	(564)	—	_	—	—	(564)	_
Gain - changes in fair value of related party contingent consideration	(9,906)	_	_	_	9,906	7,264	17,170	7,264
Restructuring costs	(549)	_		549			549	
Total operating expenses	13,557	(564)		549	9,906	7,264	17,155	30,712
Operating income (loss)	26,118	564	_	(549)	(9,906)	(7,264)	(17,155)	8,963
Investment and other income, net	977	_	133	_			133	1,110
Interest expense	(263)	—	—	_	—	—	—	(263)
Other income - changes in fair value of related party payable	768				(768)	(963)	(1,731)	(963)
Income (loss) before income taxes	27,600	564	133	(549)	(10,674)	(8,227)	(18,753)	8,847
Income tax provision (benefit)	5,921	201			(507)	(515)	(821)	5,100
Net income (loss)	\$ 21,679	\$ 363	\$ 133	\$ (549)	\$ (10,167)	\$ (7,712)	\$ (17,932)	\$ 3,747
Net income (loss) per share - diluted <sup>(1)</sup>	\$ 0.52	\$ 0.01	\$ —	\$ (0.01)	\$ (0.25)	\$ (0.19)	\$ (0.43)	\$ 0.09
Weighted average number of shares outstanding - diluted	41,339	41,339	41,339	41,339	41,339	41,339	41,339	41,339

(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full precision.



			GAAP to N	on-GAAP adjust	ments for the nine	e-months ended	September 30, 2018			
					Exclude			Include		
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Equity securities unrealized (gain)/loss impact	Amortization of debt discount and debt issuance costs	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP
Revenues:										
Product sales	\$ 82,103	\$ —	\$ —	\$ —	\$ —	\$ —	\$	\$ —	\$ —	\$ 82,103
License revenue	246									246
Total revenues	82,349	_	_	_	_	_	—	—	—	82,349
Operating expenses:										
Cost of products	13,224	_	_	_	—	_	_	_	_	13,224
Research and development expenses	33,243	—	_	—	_	_	_	_	_	33,243
Selling, general and administrative expenses	77,159	_	_	_	_	_	_	_	_	77,159
Intangible asset amortization	4,996	(4,996)	_	_	_		_	_	(4,996)	_
Gain - changes in fair value of related party contingent consideration	(17,036)	_	_	_	_	_	17,036	14,032	31,068	14,032
Restructuring costs	268	_	_	(268)		_		_	(268)	_
Total operating expenses	111,854	(4,996)	_	(268)			17,036	14,032	25,804	137,658
Operating (loss) income	(29,505)	4,996		268		_	(17,036)	(14,032)	(25,804)	(55,309)
Investment and other income, net	845	—	(153)	—	133	—	_	_	(20)	825
Interest expense	(7,577)	_	_	_	_	3,402	_	—	3,402	(4,175)
Other income - changes in fair value of related party payable	1,432	_		_	_	_	(1,432)	(2,032)	(3,464)	(2,032)
(Loss) income before income taxes	(34,805)	4,996	(153)	268	133	3,402	(18,468)	(16,064)	(25,886)	(60,691)
Income tax (benefit) provision	(3,360)	1,050			(1)		(534)	(618)	(103)	(3,463)
Net (loss) income	\$(31,445)	\$ 3,946	\$ (153)	\$ 268	\$ 134	\$ 3,402	\$ (17,934)	\$ (15,446)	\$ (25,783)	\$ (57,228)
Net income (loss) per share - diluted <sup>(1)</sup>	\$ (0.84)	\$ 0.11	\$ —	\$ 0.01	\$ —	\$ 0.09	\$ (0.48)	\$ (0.41)	\$ (0.69)	\$ (1.53)
Weighted average number of shares outstanding - diluted	37,410	37,410	37,410	37,410	37,410	37,410	37,410	37,410	37,410	37,410



		 GAAP to Non-GAAP adjustments for the nine-months ended September 30, 2017															
						Ex	clud	le						Include			
	GAAP	itangible asset ortization	e	Foreign xchange (ain)/loss		structuring impacts	ac adj	urchase counting justments - FSC	1	License revenue ljustment	r I	Contingent elated party payable fair value neasurements	re	ontingent lated party payable id/accrued	ad	Total justments	djusted GAAP
Revenues:																	
Product sales	\$ 138,009	\$ _	\$	_	\$	_	\$	_	\$	_	\$		\$	_	\$	_	\$ 138,009
License revenue	484			_					_	1,100						1,100	1,584
Total revenues	138,493	_		_		_		_		1,100		_		_		1,100	139,593
Operating expenses:																	
Cost of products	12,253	—		_		—		(46)		_		_		_		(46)	12,207
Research and development expenses	22,093	_		_		_		_		_		_		_			22,093
Selling, general and administrative expenses	35,804	_		_		_		_		_		_		_		_	35,804
Intangible asset amortization	1,692	(1,692)		_		_		_		_		_		_		(1,692)	_
Gain - changes in fair value of related party contingent consideration	(30,107)	_		_		_		_		_		30,107		25,396		55,503	25,396
Restructuring costs	3,173			_		(3,173)			_							(3,173)	_
Total operating expenses	44,908	(1,692)		_		(3,173)		(46)				30,107		25,396		50,592	95,500
Operating income (loss)	93,585	1,692		_		3,173		46		1,100		(30,107)		(25,396)		(49,492)	44,093
Investment and other income, net	2,562	_		127		—		_		—		_		_		127	2,689
Interest expense	(789)	—		—		—		—		—		—		—		—	(789)
Other income - changes in fair value of related party payable	2,988	_		_		_		_		_		(2,988)		(3,428)		(6,416)	(3,428)
Income (loss) before income taxes	98,346	1,692		127		3,173		46		1,100		(33,095)		(28,824)		(55,781)	42,565
Income tax provision (benefit)	21,830	603		—		_		17		—		(1,776)		(1,822)		(2,978)	18,852
Net income (loss)	\$ 76,516	\$ 1,089	\$	127	\$	3,173	\$	29	\$	1,100	\$	(31,319)	\$	(27,002)	\$	(52,803)	\$ 23,713
Net income (loss) per share - diluted <sup>(1)</sup>	\$ 1.81	\$ 0.03	\$	—	\$	0.08	\$	_	\$	0.03	\$	(0.74)	\$	(0.64)	\$	(1.25)	\$ 0.56
Weighted average number of shares outstanding - diluted	42,194	42,194		42,194		42,194		42,194		42,194		42,194		42,194		42,194	42,194

(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full precision.