



Alkermes plc Reports Third Quarter 2020 Financial Results and Raises 2020 Financial Expectations

October 29, 2020

- Company Reports Third Quarter Revenues of \$265.0 Million, GAAP Net Loss per Share of \$0.00 and Basic and Diluted Non-GAAP Earnings per Share of \$0.26 -

- ARISTADA® Net Sales of \$62.4 Million Reflect 16% Year-Over-Year Growth -

- VIVITROL® Net Sales Increased 12% Sequentially to \$80.3 Million -

DUBLIN, Oct. 29, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the third quarter of 2020 and provided updated financial expectations for full-year 2020.

"Over the past several months, we achieved a number of important milestones in our development programs against the backdrop of strong commercial execution and disciplined management of our expenses. The positive outcome of the ALKS 3831 FDA Advisory Committee meeting and the presentation of accumulating data for ALKS 4230, including monotherapy responses observed in melanoma, were significant achievements that underscore the potential value of these investigational medicines," said Richard Pops, Chief Executive Officer of Alkermes. "As we look ahead, we will continue to focus on our strategic imperatives: commercial execution, including preparations for the potential launch of ALKS 3831, aggressive development of our pipeline candidates, and efficient management of our operating cost structure, as we position the company for long-term value creation."

Quarter Ended Sept. 30, 2020 Financial Highlights

- Total revenues for the quarter were \$265.0 million, compared to \$255.2 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$0.1 million for the quarter, or a GAAP net loss per share of \$0.00. This compared to GAAP net loss of \$52.9 million, or a GAAP net loss per share of \$0.34, for the same period in the prior year.
- Non-GAAP net income was \$41.5 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.26. This compared to non-GAAP net loss of \$7.0 million, or a non-GAAP basic and diluted loss per share of \$0.04, for the same period in the prior year.

Quarter Ended Sept. 30, 2020 Financial Results

Revenues

- Net sales of proprietary products were \$142.7 million, compared to \$138.8 million for the same period in the prior year.
 - Net sales of VIVITROL were \$80.3 million, compared to \$85.2 million for the same period in the prior year, representing a decrease of 6%, due primarily to COVID-19 pandemic-related disruptions. Sequentially, net sales of VIVITROL increased 12%, driven by increased demand during the quarter.
 - Net sales of ARISTADAⁱ were \$62.4 million, compared to \$53.6 million for the same period in the prior year, representing an increase of 16%, driven primarily by continued growth of the ARISTADA provider base and growth of the ARISTADA two-month dose.
- Manufacturing and royalty revenues were \$120.4 million, compared to \$103.8 million for the same period in the prior year.
 - Manufacturing and royalty revenues from RISPERDAL CONSTA[®], INVEGA SUSTENNA[®]/XEPLION[®] and INVEGA TRINZA[®]/TREVICTA[®] were \$87.9 million, compared to \$76.7 million for the same period in the prior year, primarily driven by an increase in royalty revenue from INVEGA SUSTENNA and the timing of manufacturing shipments of RISPERDAL CONSTA.

Costs and Expenses

- Total operating expenses were \$275.7 million, compared to \$308.9 million for the same period in the prior year. This decrease reflects the impact of the restructuring implemented in 2019 and expense management measures in 2020.
 - Research and Development (R&D) expenses were \$95.0 million, compared to \$107.7 million for the same period in the prior year.
 - Selling, General and Administrative (SG&A) expenses were \$127.7 million, compared to \$148.7 million for the same period in the prior year.

Balance Sheet

- At Sept. 30, 2020, Alkermes recorded cash, cash equivalents and total investments of \$597.2 million, compared to \$539.6 million at June 30, 2020, driven by the company's operating results and changes in working capital. The company's total debt outstanding as of Sept. 30, 2020 was \$275.5 million under its term loan, which matures in March 2023.

"Our third quarter results reflect strong commercial execution, with the sequential growth of both VIVITROL and ARISTADA net sales within a complex and dynamic COVID-19 market environment. Today, we are pleased to be raising our financial guidance for 2020 to reflect this solid performance. Importantly, expectations for 2020 non-GAAP net income are back in line with the expectations provided in February prior to the impact of COVID-19, primarily due to disciplined management of our expenses," commented James Frates, Chief Financial Officer of Alkermes. "As we approach the end of 2020, we believe we are well-positioned to execute on our strategic imperatives to drive long-term profitability and growth."

Financial Expectations for 2020

The following financial expectations for 2020 are based on recent trends and assume that treatment provider practices and patient access to the company's commercial products continue to normalize. New COVID-19-related restrictions or a resurgence of COVID-19 could impact the company's ability to meet these expectations. All line items are according to GAAP, except as otherwise noted.

<i>In millions (except per share amounts)</i>	Current 2020 Expectation		Previous Expectation	
	(Provided 10/29/20)		(Provided 7/29/20)	
Total Revenue	\$1,010 – \$1,035		\$965 – \$1,005	
VIVITROL Net Sales	\$305 – \$315		\$270 – \$300	
ARISTADA Net Sales	\$230 – \$240		\$220 – \$235	
Cost of Goods Sold	\$180 – \$190		\$180 – \$190	
R&D Expenses	\$375 – \$390		\$370 – \$395	
SG&A Expenses	\$530 – \$545		\$525 – \$550	
Amortization of Intangible Assets	~\$40		~\$40	
Other Income, Net	~\$30		\$10 – \$15	
Income Tax Expense	\$10 – \$15		\$10 – \$15	
GAAP Net Loss	(\$95) – (\$115)		(\$145) – (\$175)	
GAAP Net Loss per Share	(\$0.60) – (\$0.72)		(\$0.91) – (\$1.10)	
Non-GAAP Net Income	\$50 – \$70		\$0 – \$30	
Non-GAAP Diluted EPS	\$0.31 – \$0.43		\$0.00 – \$0.19	
Capital Expenditures	~\$35		~\$35	

Recent Events

- Psychiatry portfolio
 - In October 2020, announced positive vote outcomes from the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, appointed by the U.S. Food and Drug Administration (FDA), on questions relating to ALKS 3831 for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder. The joint advisory committee's recommendations, while not binding, will be considered by the FDA in its review of the ALKS 3831 New Drug Application (NDA). The Prescription Drug User Fee Act (PDUFA) target action date for the ALKS 3831 NDA is Nov. 15, 2020.
 - In September 2020, presented new real-world outcomes research and clinical data related to Alkermes' psychiatry portfolio at the Psych Congress 2020 Virtual Experience, including new outcomes research that analyzed treatment challenges of second-generation antipsychotics, such as weight gain and treatment interruptions, for patients living with schizophrenia or bipolar I disorder.
 - In August 2020, announced the publication in the peer-reviewed *American Journal of Psychiatry* of results from the phase 3 ENLIGHTEN-2 clinical trial of ALKS 3831. ENLIGHTEN-2 was a six-month study evaluating the weight gain profile of ALKS 3831 compared to olanzapine in 561 patients with stable schizophrenia. Positive topline data from the ENLIGHTEN-2 study were first reported in November 2018.
- ALKS 4230
 - In September 2020, presented new clinical data updates from ARTISTRY-1, an ongoing phase 1/2 study evaluating Alkermes' investigational engineered interleukin-2 variant immunotherapy, ALKS 4230, administered intravenously as monotherapy and in combination with the PD-1 inhibitor pembrolizumab in patients with refractory solid tumors, at the 2020 European Society for Medical Oncology (ESMO) Virtual Congress. The company also announced the expansion of the ARTISTRY-1 monotherapy melanoma cohort based on the achievement of protocol-defined efficacy response criteria.
 - In August 2020, announced the initiation of ARTISTRY-3, a phase 2 study evaluating the clinical and immunologic effects of ALKS 4230 monotherapy administered intravenously on the tumor microenvironment in a variety of advanced, malignant solid tumors.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (12:00 p.m. GMT) on Thursday, Oct. 29, 2020, to discuss these financial results, financial expectations, and provide an update on the company. The webcast may be accessed on the Investors section of Alkermes' website at www.alkermes.com. The conference call may be accessed by dialing +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call will be available from 11:00 a.m. ET (3:00 p.m. GMT) on Thursday, Oct. 29, 2020, through Thursday, Nov. 5, 2020, and may be accessed by visiting Alkermes' website or by dialing +1 877 660 6853 for U.S. callers and

+1 201 612 7415 for international callers. The replay conference ID is 13712082.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on addiction and schizophrenia, and a pipeline of product candidates in development for schizophrenia, bipolar I disorder, neurodegenerative disorders and cancer. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with GAAP, including non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income (loss) adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; changes in the fair value of the contingent consideration; certain other one-time or non-cash items; and the income tax effect of these reconciling items.

The company's management and the Board utilize these non-GAAP financial measures to evaluate the company's performance. The company provides these non-GAAP measures of the company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share should not be considered measures of the company's liquidity.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company's expectations concerning future financial and operating performance, business plans or prospects, including the anticipated ongoing impacts of COVID-19 on the company's business and financial performance, the company's assumptions with respect to continued normalization of patient and healthcare provider practices, and the company's ability to drive long-term value creation and profitability; the potential therapeutic and commercial value of the company's marketed and development products; the company's expectations concerning future development activities for the company's development candidates; the company's expectations regarding the FDA's review of the ALKS 3831 NDA, including the FDA's PDUFA target action date for the NDA; and expectations concerning the company's commercial activities, including the potential launch of ALKS 3831. The company cautions that forward-looking statements are inherently uncertain. The forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the impacts of the ongoing COVID-19 pandemic and continued efforts to mitigate its spread on the company's business, results of operations or financial condition, including: impacts on the vendors or distribution channels in its supply chain, and the company's ability to continue to manufacture its products; impacts on its ability to continue its discovery activities; impacts on the conduct of its clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites and monitoring of data; impacts on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia and on patient and healthcare provider access to the company's medicines; impacts on the regulatory agencies with which the company interacts in the development, review, approval and commercialization of its medicines; impacts on reimbursement for the company's products, including its Medicaid rebate liability, and for services related to the use of its products; and impacts on the U.S., Irish and/or global economies more broadly; the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of the company's products or products using the company's proprietary technologies, which may lead to competition from generic drug manufacturers; clinical development activities may not be completed on time or at all; the results of the company's clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products, such as decisions not to approve the company's NDAs, including the NDA for ALKS 3831; data from clinical trials may be interpreted by the FDA in different ways than the company or an advisory committee interprets it; the FDA may not agree with the company's regulatory approval strategies or components of its ALKS 3831 NDA or other regulatory filings, including the company's clinical trial designs, conduct and methodologies, manufacturing processes and facilities, and the adequacy of the data and other information included in its filings to meet the FDA's requirements for approval, including the risk/benefit profile of the company's product candidates; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to governmental payers; the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2019, the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

Trademarks

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland Limited; and RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson.

(tables follow)

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019
Revenues:		
Product sales, net	\$ 142,658	\$ 138,774
Manufacturing and royalty revenues	120,351	103,783
Research and development revenue	953	12,686
License revenue	1,050	—
Total Revenues	265,012	255,243
Expenses:		
Cost of goods manufactured and sold	43,129	42,319
Research and development	94,980	107,671
Selling, general and administrative	127,653	148,701
Amortization of acquired intangible assets	9,917	10,173
Total Expenses	275,679	308,864
Operating Loss	(10,667)	(53,621)
Other Income (Expense), net:		
Interest income	1,376	3,509
Interest expense	(1,811)	(3,385)
Change in the fair value of contingent consideration	3,926	1,300
Other income (expense), net	9,368	(1,664)
Total Other Income (Expense), net	12,859	(240)
Income (Loss) Before Income Taxes	2,192	(53,861)
Provision (Benefit) for Income Taxes	2,326	(983)
Net Loss — GAAP	\$ (134)	\$ (52,878)

(Loss) Earnings Per Share:

GAAP loss per share — basic and diluted	\$ (0.00)	\$ (0.34)
Non-GAAP earnings (loss) per share — basic and diluted	\$ 0.26	\$ (0.04)

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP	159,062	157,199
Basic — Non-GAAP	159,062	157,199
Diluted — Non-GAAP	160,335	157,199

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:

Net Loss — GAAP	\$ (134)	\$ (52,878)
Adjustments:		
Share-based compensation expense	22,618	26,729
Depreciation expense	10,663	10,173
Amortization expense	9,917	10,173
Income tax effect related to reconciling items	2,174	155
Non-cash net interest expense	166	168
Change in the fair value of contingent consideration	(3,926)	(1,300)
Change in the fair value of warrants	—	(206)
Non-GAAP Net Income (Loss)	\$ 41,478	\$ (6,986)

Condensed Consolidated Statements of Operations - GAAP
(In thousands, except per share data)

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Revenues:		
Product sales, net	\$ 402,799	\$ 374,890
Manufacturing and royalty revenues	353,107	340,595
Research and development revenue	1,805	41,732
License Revenue	1,050	1,000
Total Revenues	758,761	758,217
Expenses:		
Cost of goods manufactured and sold	135,394	133,903
Research and development	282,481	314,676
Selling, general and administrative	393,049	444,996
Amortization of acquired intangible assets	29,535	30,187
Total Expenses	840,459	923,762
Operating Loss	(81,698)	(165,545)
Other Income (Expense), net:		
Interest income	5,924	10,785
Interest expense	(6,790)	(10,405)
Change in the fair value of contingent consideration	16,626	(27,800)

Other income (expense), net	11,047	(1,534)
Total Other Income (Expense), net	26,807	(28,954)
Loss Before Income Taxes	(54,891)	(194,499)
Provision (Benefit) for Income Taxes	13,328	(3,233)
Net Loss — GAAP	\$ (68,219)	\$ (191,266)

(Loss) Earnings Per Share:

GAAP loss per share — basic and diluted	\$ (0.43)	\$ (1.22)
Non-GAAP earnings (loss) per share — basic and diluted	\$ 0.33	\$ (0.12)

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP	158,685	156,845
Basic — Non-GAAP	158,685	156,845
Diluted — Non-GAAP	159,467	156,845

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:

Net Loss — GAAP	\$ (68,219)	\$ (191,266)
Adjustments:		
Share-based compensation expense	65,277	79,590
Depreciation expense	31,991	29,715
Amortization expense	29,535	30,187
Income tax effect related to reconciling items	8,971	5,170
Non-cash net interest expense	500	505
Change in the fair value of contingent consideration	(16,626)	27,800
Acquisition of IPR&D	674	—
Change in the fair value of warrants	—	(907)
Non-GAAP Net Income (Loss)	\$ 52,103	\$ (19,206)

**Condensed Consolidated Balance Sheets
(In thousands)**

	September 30, 2020	December 31, 2019
Cash, cash equivalents and total investments	\$ 597,156	\$ 614,370
Receivables	265,644	257,086
Contract assets	14,395	8,386
Inventory	122,823	101,803
Prepaid expenses and other current assets	52,697	59,716
Property, plant and equipment, net	355,215	362,168
Intangible assets, net and goodwill	213,981	243,516
Other assets	254,909	158,358
Total Assets	\$ 1,876,820	\$ 1,805,403
Long-term debt — current portion	\$ 2,843	\$ 2,843
Other current liabilities	375,308	388,269
Long-term debt	272,663	274,295
Contract liabilities — long-term	18,635	22,068
Other long-term liabilities	123,013	32,486
Total shareholders' equity	1,084,357	1,085,442
Total Liabilities and Shareholders' Equity	\$ 1,876,820	\$ 1,805,403
Ordinary shares outstanding (in thousands)	159,105	157,779

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, which the company intends to file in October 2020.

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

(In millions, except per share data)	Amount	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	\$ (105.0)	159	\$ (0.66)
Adjustments:			
Share-based compensation expense	92.5		
Depreciation expense	42.5		
Amortization expense	40.0		
Income tax effect related to reconciling items	6.5		
Non-cash net interest expense	1.0		

Change in the fair value of contingent consideration	(17.5)			
Projected Net Income — Non-GAAP	<u>\$ 60.0</u>	161	\$	0.37

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.

ⁱ The term "ARISTADA" as used in this press release refers to ARISTADA and ARISTADA INITIO, unless the context indicates otherwise.

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