



## Alkermes plc Reports Second Quarter 2020 Financial Results and Issues 2020 Financial Expectations

July 29, 2020

**-- Company Reports Second Quarter Revenues of \$247.5 Million, GAAP Net Loss per Share of \$0.19 and Diluted Non-GAAP Earnings per Share of \$0.06 --**

**-- ARISTADA® Net Sales Increased 21% Year-Over-Year to \$58.8 Million --**

**-- VIVITROL® Net Sales of \$71.6 Million Reflect Impact of COVID-19-Related Treatment Disruptions --**

**-- Company Announces Board Declassification Proposal and Board Refreshment Process --**

DUBLIN, July 29, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the second quarter of 2020 and provided updated financial expectations for full-year 2020. The company had previously withdrawn its 2020 financial expectations due to uncertainties regarding the impact of the COVID-19 pandemic on its business.

"During the second quarter, we adapted in response to the changing conditions in a complex environment. As we enter the second half of 2020, we are focused on three strategic imperatives. The first is commercial execution, as we drive to maximize the opportunities for ARISTADA® and VIVITROL® and prepare for the potential launch of ALKS 3831. The second is aggressive development of our pipeline programs, focusing on high-value opportunities that we believe have the potential to address patient needs and drive significant value in the near- and long-term. ALKS 4230, our lead oncology candidate, is the most prominent of these opportunities. The third is efficient management of our operating structure, with a focus on rigorous expense management and careful prioritization of our investments," said Richard Pops, Chief Executive Officer of Alkermes.

"We distinguish ourselves from other biopharmaceutical companies through our efforts in serious mental illness and addiction — chronic, highly prevalent conditions that affect millions of people and represent some of the most challenging public health issues of our time. We have built our organization with purpose and invested in specialized commercial capabilities to navigate fragmented treatment systems as we help address the complex challenges that patients with these diseases face," continued Mr. Pops. "As the nation's response to COVID-19 continues, it is critical that we work to mitigate the pandemic's secondary impacts related to social isolation, economic hardship and anxiety. For many patients struggling with serious mental illness and addiction, the current environment has amplified the barriers to treatment that Alkermes has worked for many years to address. We believe it is our responsibility to help ensure that the treatment system continues to function for these patients."

### Quarter Ended June 30, 2020 Financial Highlights

- Total revenues for the quarter were \$247.5 million, compared to \$279.9 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$29.4 million for the quarter, or a GAAP net loss per share of \$0.19. This compared to GAAP net loss of \$42.0 million, or a GAAP net loss per share of \$0.27, for the same period in the prior year.
- Non-GAAP net income was \$8.9 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.06. This compared to non-GAAP net income of \$13.7 million, or a non-GAAP basic and diluted earnings per share of \$0.09, for the same period in the prior year.

### Quarter Ended June 30, 2020 Financial Results

#### Revenues

- Net sales of proprietary products were \$130.4 million, compared to \$136.6 million for the same period in the prior year.
  - Net sales of VIVITROL were \$71.6 million, compared to \$88.2 million for the same period in the prior year, representing a decrease of approximately 19%, driven primarily by a decline in new patient starts and more restricted access to healthcare providers that resulted from COVID-19-related disruptions.
  - Net sales of ARISTADA<sup>i</sup> were \$58.8 million, compared to \$48.4 million for the same period in the prior year, representing an increase of approximately 21% driven primarily by increased breadth of the ARISTADA provider base and growth of the ARISTADA two-month dose.
- Manufacturing and royalty revenues were \$116.5 million, compared to \$127.9 million for the same period in the prior year.
  - Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$83.1 million, compared to \$91.9 million for the same period in the prior year, primarily driven by a decrease in manufacturing and royalty revenues related to RISPERDAL CONSTA.

#### Costs and Expenses

- Total operating expenses were \$281.2 million, compared to \$315.8 million for the same period in the prior year.
  - Research and Development (R&D) expenses were \$94.2 million, compared to \$104.4 million for the same period in the prior year.
  - Selling, General and Administrative (SG&A) expenses were \$132.0 million, compared to \$155.1 million for the same period in the prior year.

#### Balance Sheet

- At June 30, 2020, Alkermes recorded cash, cash equivalents and total investments of \$539.6 million, compared to \$549.7 million at March 31, 2020. Cash on hand at June 30, 2020 significantly exceeded the company's total debt outstanding of \$276.1 million under its term loan, which matures in March 2023.

"Our second quarter results reflect solid execution across the business. The performance of the ARISTADA product family, together with disciplined management of expenses, partially offset the negative impact on VIVITROL net sales that resulted from COVID-19-related decreases in patient visits to healthcare providers and treatment centers. With increased visibility into the expected impact of COVID-19 on our commercial portfolio, today we are issuing financial expectations for 2020 that reflect current trends and underscore our commitment to driving non-GAAP profitability," commented James Frates, Chief Financial Officer of Alkermes. "Over the past five years, we have grown our topline while investing in the future growth drivers of our business. Directly as a result of those investments, we established VIVITROL as an important therapeutic option for patients with opioid and alcohol dependence; we secured FDA approvals for the ARISTADA product family; we developed ALKS 3831 and submitted a New Drug Application for schizophrenia and bipolar I disorder; we built commercial psychiatry capabilities that support the growth of ARISTADA and which are also fully leverageable for ALKS 3831; we successfully developed VUMERITY® and entered into a commercial collaboration that will provide 100% gross margin royalty revenues from net sales; we advanced development of ALKS 4230 while retaining optionality for strategic collaboration; and, we acquired a platform of histone deacetylase (HDAC) inhibitors that we believe will provide compelling pipeline opportunities in neurodegeneration and oncology. We are focused on executing our business strategy and believe these investments have positioned the business to drive long-term profitability and value creation."

#### Financial Expectations for 2020

The following financial expectations for 2020 reflect the anticipated net impacts of the COVID-19 pandemic on Alkermes' operating and financial results. Alkermes anticipates that the negative impact of COVID-19 on VIVITROL net sales will be partially offset by a decrease in operating expenses, notably within R&D. The ranges provided are based on current trends and assume that treatment provider practices and patient flow will continue to normalize. Additional wide-spread COVID-19-related restrictions or resurgence of COVID-19 could negatively 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>	<b>Current 2020 Expectation</b> (Provided 7/29/20)	<b>Pre-COVID-19 Expectation</b> (Provided 2/13/20; Suspended 4/29/20)
Total Revenue	\$965 – \$1,005	\$1,030 – \$1,080
VIVITROL Net Sales	\$270 – \$300	\$340 – \$355
ARISTADA Net Sales	\$220 – \$235	\$220 – \$235
Cost of Goods Sold	\$180 – \$190	\$185 – \$195
R&D Expenses	\$370 – \$395	\$405 – \$430
SG&A Expenses	\$525 – \$550	\$535 – \$560
Amortization of Intangible Assets	~\$40	~\$40
Other Income, Net	\$10 – \$15	–
Income Tax Expense	\$10 – \$15	\$0 – \$10
GAAP Net Loss	(\$145) – (\$175)	(\$130) – (\$160)
GAAP Net Loss per Share	(\$0.91) – (\$1.10)	(\$0.82) – (\$1.01)
Non-GAAP Net Income	\$0 – \$30	\$40 – \$70
Non-GAAP Basic EPS	\$0.00 – \$0.19	\$0.25 – \$0.44
Non-GAAP Diluted EPS	\$0.00 – \$0.19	\$0.25 – \$0.43
Capital Expenditures	~\$35	\$45 – \$55

#### Governance Update

"Over the past 12 months, we conducted extensive shareholder outreach and engaged with shareholders representing approximately 60% in value of our outstanding ordinary shares. The Board values the views of our shareholders and, after considering their feedback, is taking actions to further strengthen our business and corporate governance practices. The Board believes these actions will help to position the company for long-term growth as we execute on our strategy," said David Anstice, Lead Independent Director of the Alkermes Board of Directors (the Board).

The company announced today that it plans to take a series of actions as part of its commitment to corporate governance best practices and regular Board refreshment.

- First, the Board will recommend that shareholders approve, at the company's 2021 Annual General Meeting of Shareholders, an amendment to the company's Articles of Association to declassify the Board. Currently, the Board has three classes of directors, with directors in each class elected to three-year terms. Once the Board is declassified, the directors will be combined into a single class elected annually.
- Second, the Board has engaged a leading recruitment firm to identify independent director candidates whose experience and expertise offer valuable insights and strategic leadership at this stage in Alkermes' evolution. As part of this process, the company expects certain of its longer-serving directors will retire from the Board. This Board refreshment process will

continue and build on the efforts undertaken by the company in the fall of 2019 that led to the addition of two highly-qualified, independent directors, Dr. Richard Gaynor and Mr. Andy Wilson, to the Board.

### **Recent Events**

- Schizophrenia portfolio
  - In May 2020, presented new research from the company's schizophrenia portfolio at the American Society of Clinical Psychopharmacology (ASCP) 2020 Annual Meeting, including data from patient-reported evaluations relating to treatment with ALKS 3831 and satisfaction data relating to treatment with ARISTADA.
  - In July 2020, announced a new survey conducted by The Harris Poll for Alkermes, which explored the current use and future potential of telepsychiatry services during and after the COVID-19 pandemic.
- ALKS 4230
  - In June 2020, presented positive preclinical data from a study designed to evaluate the combination potential of ALKS 4230, Alkermes' investigational engineered interleukin-2 (IL-2) variant immunotherapy, with lucitanib, Clovis Oncology, Inc.'s investigational angiogenesis inhibitor, at the American Association for Cancer Research (AACR) Virtual Annual Meeting II.
- Corporate citizenship
  - In June 2020, announced that 10 nonprofit organizations were awarded grants from the company's COVID-19 Relief Fund, a special edition of the company's signature Alkermes Inspiration Grants<sup>®</sup> program, that was established to assist nonprofit organizations in their work to rapidly address pandemic-related needs for people living with addiction, serious mental illness, or cancer.
  - In July 2020, published Alkermes' latest Corporate Responsibility Report which outlines how the company integrates environmental, social and governance considerations into all aspects of its business. A copy of the report is available on the Responsibility section of Alkermes' website.

### **Conference Call**

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (1:00 p.m. BST) on Wednesday, July 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](http://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 (4:00 p.m. BST) on Wednesday, July 29, 2020, through Wednesday, Aug. 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 13707215.

### **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](http://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 normalization of patient and healthcare provider practices, the expected growth drivers of the company's business, and the company's ability to drive significant value creation and long-term growth and profitability; the potential therapeutic and commercial value of the company's marketed and development products and the company's potential contributions to supporting patient access to

such products; the company's plans for, and expectations relating to, corporate governance changes, including the proposed declassification and refreshment of the Board; expectations concerning future development activities for the company's development candidates; and expectations and timelines concerning the company's commercial activities and capabilities, including in relation to the potential launch of ALKS 3831 following U.S. Food and Drug Administration's ("FDA") review and potential approval of the new drug application ("NDA") for 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, including decisions not to approve the company's NDAs; data from clinical trials may be interpreted by the FDA in different ways than the company interprets it; the FDA may not agree with the company's regulatory approval strategies or components of its 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; 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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q 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](http://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<sup>®</sup> is a registered trademark of Alkermes, Inc.; ARISTADA<sup>®</sup> and ARISTADA INITIO<sup>®</sup> are registered trademarks of Alkermes Pharma Ireland Limited; VUMERITY<sup>®</sup> is a registered trademark of Biogen Inc., used by Alkermes under license; and RISPERDAL CONSTA<sup>®</sup>, INVEGA SUSTENNA<sup>®</sup>, XEPLION<sup>®</sup>, INVEGA TRINZA<sup>®</sup> and TREVICTA<sup>®</sup> are registered trademarks of Johnson & Johnson.

(tables follow)

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

#### Alkermes plc and Subsidiaries Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended Three Months Ended	
	June 30, 2020	June 30, 2019
Revenues:		
Product sales, net	\$ 130,415	\$ 136,635
Manufacturing and royalty revenues	116,505	127,897
Research and development revenue	609	14,340
License revenue	—	1,000
Total Revenues	<u>247,529</u>	<u>279,872</u>
Expenses:		
Cost of goods manufactured and sold	45,053	46,223
Research and development	94,222	104,435
Selling, general and administrative	132,025	155,075
Amortization of acquired intangible assets	9,890	10,062
Total Expenses	<u>281,190</u>	<u>315,795</u>
Operating Loss	<u>(33,661)</u>	<u>(35,923)</u>
Other Income (Expense), net:		
Interest income	1,788	3,706
Interest expense	(2,122)	(3,520)
Change in the fair value of contingent consideration	5,900	(6,500)
Other income, net	2,337	1,851
Total Other Income (Expense), net	<u>7,903</u>	<u>(4,463)</u>
Loss Before Income Taxes	<u>(25,758)</u>	<u>(40,386)</u>
Income Tax Provision	3,673	1,604
<b>Net Loss — GAAP</b>	<u>\$ (29,431)</u>	<u>\$ (41,990)</u>
<b>(Loss) Earnings Per Share:</b>		
GAAP loss per share — basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.27)</u>

Non-GAAP earnings per share — basic and diluted	\$	0.06	\$	0.09
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**Weighted Average Number of Ordinary Shares Outstanding:**

Basic and diluted — GAAP	158,895	156,991
Basic — Non-GAAP	158,895	156,991
Diluted — Non-GAAP	159,275	158,987

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

<b>Net Loss — GAAP</b>	\$	(29,431)	\$	(41,990)
Adjustments:				
Share-based compensation expense		22,846		28,245
Depreciation expense		10,447		9,852
Amortization expense		9,890		10,062
Income tax effect related to reconciling items		877		2,043
Non-cash net interest expense		167		168
Change in the fair value of contingent consideration		(5,900)		6,500
Change in the fair value of warrants and equity method investments		—		(1,134)
<b>Non-GAAP Net Income</b>	\$	8,896	\$	13,746

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

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Revenues:		
Product sales, net	\$ 260,141	\$ 236,116
Manufacturing and royalty revenues	232,756	236,812
Research and development revenue	852	29,046
License Revenue	—	1,000
Total Revenues	493,749	502,974
Expenses:		
Cost of goods manufactured and sold	92,264	91,584
Research and development	187,501	207,005
Selling, general and administrative	265,397	296,295
Amortization of acquired intangible assets	19,618	20,014
Total Expenses	564,780	614,898
Operating Loss	(71,031)	(111,924)
Other Income (Expense), net:		
Interest income	4,548	7,276
Interest expense	(4,979)	(7,020)
Change in the fair value of contingent consideration	12,700	(29,100)
Other income, net	1,679	130
Total Other Income (Expense), net	13,948	(28,714)
Loss Before Income Taxes	(57,083)	(140,638)
Provision (Benefit) for Income Taxes	11,002	(2,250)
<b>Net Loss — GAAP</b>	\$ (68,085)	\$ (138,388)

**(Loss) Earnings Per Share:**

GAAP loss per share — basic and diluted	\$	(0.43)	\$	(0.88)
Non-GAAP earnings (loss) per share — basic and diluted	\$	0.07	\$	(0.08)

**Weighted Average Number of Ordinary Shares Outstanding:**

Basic and diluted — GAAP	158,495	156,665
Basic — Non-GAAP	158,495	156,665
Diluted — Non-GAAP	159,151	156,665

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

<b>Net Loss — GAAP</b>	\$	(68,085)	\$	(138,388)
Adjustments:				
Share-based compensation expense		42,659		52,861
Depreciation expense		21,328		19,542
Amortization expense		19,618		20,014
Income tax effect related to reconciling items		6,797		5,015
Non-cash net interest expense		334		337
Change in the fair value of contingent consideration		(12,700)		29,100
Acquisition of IPR&D		674		—
Change in the fair value of warrants and equity method investments		—		(701)
<b>Non-GAAP Net Income (Loss)</b>	\$	10,625	\$	(12,220)

<b>Condensed Consolidated Balance Sheets (In thousands)</b>	<b>June 30, 2020</b>	<b>December 31, 2019</b>
Cash, cash equivalents and total investments	\$ 539,596	\$ 614,370
Receivables	237,393	257,086
Contract assets	9,240	8,386
Inventory	116,458	101,803
Prepaid expenses and other current assets	51,705	59,716
Property, plant and equipment, net	361,807	362,168
Intangible assets, net and goodwill	223,898	243,516
Other assets	262,240	158,358
<b>Total Assets</b>	<b>\$ 1,802,337</b>	<b>\$ 1,805,403</b>
Long-term debt — current portion	\$ 2,843	\$ 2,843
Other current liabilities	318,571	388,269
Long-term debt	273,207	274,295
Contract liabilities — long-term	18,881	22,068
Other long-term liabilities	126,989	32,486
Total shareholders' equity	1,061,846	1,085,442
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,802,337</b>	<b>\$ 1,805,403</b>
Ordinary shares outstanding (in thousands)	159,028	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 six months ended June 30, 2020, which the company intends to file in July 2020.

#### 2020 Guidance — GAAP to Non-GAAP Adjustments

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:

<b>(In millions, except per share data)</b>	<b>Amount</b>	<b>Shares</b>	<b>(Loss) Earnings Per Share</b>
Projected Net Loss — GAAP	\$ (160.0)	159	\$ (1.01)
Adjustments:			
Share-based compensation expense		97.5	
Depreciation expense		44.0	
Amortization expense		40.0	
Income tax effect related to reconciling items		5.0	
Non-cash net interest expense		1.0	
Change in the fair value of contingent consideration		(12.5)	
Projected Net Income — Non-GAAP	<u>\$ 15.0</u>	161	\$ 0.09

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

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