

**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): October 29, 2020

**ALKERMES PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction  
of incorporation)

**001-35299**  
(Commission  
File Number)

**98-1007018**  
(IRS Employer  
Identification No.)

**Connaught House, 1 Burlington Road  
Dublin 4, Ireland D04 C5Y6**  
(Address of principal executive offices)

**Registrant's telephone number, including area code: + 353-1-772-8000**

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 (see General Instruction A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, \$0.01 par value	ALKS	Nasdaq Global Select Market

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.

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

On October 29, 2020, Alkermes plc (the “Company”) announced financial results for the three and nine months ended September 30, 2020 and updated certain financial expectations for the year ending December 31, 2020. Copies of the related press release and the investor presentation to be displayed during the Company’s conference call on October 29, 2020 discussing such financial results and updated financial expectations are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively. This information, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Alkermes plc dated October 29, 2020 announcing financial results for the three and nine months ended September 30, 2020 and updating certain financial expectations for the year ending December 31, 2020.</a>
99.2	<a href="#">Investor presentation to be displayed by Alkermes plc on October 29, 2020.</a>
104	Cover page interactive data file (embedded within the Inline XBRL document).

**SIGNATURE**

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.

**ALKERMES PLC**

Date: October 29, 2020

By: /s/ James M. Frates  
James M. Frates  
Senior Vice President and Chief Financial Officer (Principal Financial Officer)

Alkermes Contacts:

For Investors: Sandy Coombs +1 781 609 6377  
 For Media: Katie Joyce +1 781 249 8927

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

— *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, Ireland, Oct. 29, 2020** — 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 ARISTADA<sup>1</sup> 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>	<b>Current 2020 Expectation</b> <small>(Provided 10/29/20)</small>	<b>Previous Expectation</b> <small>(Provided 7/29/20)</small>
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](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 (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](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 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](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® 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)

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<sup>1</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 September 30, 2020	Three Months Ended September 30, 2019
<b>Revenues:</b>		
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	<u>265,012</u>	<u>255,243</u>
<b>Expenses:</b>		
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	<u>275,679</u>	<u>308,864</u>
Operating Loss	<u>(10,667)</u>	<u>(53,621)</u>
<b>Other Income (Expense), net:</b>		
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	<u>12,859</u>	<u>(240)</u>
Income (Loss) Before Income Taxes	<u>2,192</u>	<u>(53,861)</u>
Provision (Benefit) for Income Taxes	<u>2,326</u>	<u>(983)</u>
<b>Net Loss — GAAP</b>	<u>\$ (134)</u>	<u>\$ (52,878)</u>
<b>(Loss) Earnings Per Share:</b>		
GAAP loss per share — basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.34)</u>
Non-GAAP earnings (loss) per share — basic and diluted	<u>\$ 0.26</u>	<u>\$ (0.04)</u>
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	<u>159,062</u>	<u>157,199</u>
Basic — Non-GAAP	<u>159,062</u>	<u>157,199</u>
Diluted — Non-GAAP	<u>160,335</u>	<u>157,199</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:		
<b>Net Loss — GAAP</b>	\$ (134)	\$ (52,878)
<b>Adjustments:</b>		
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)
<b>Non-GAAP Net Income (Loss)</b>	<u>\$ 41,478</u>	<u>\$ (6,986)</u>

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

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
<b>Revenues:</b>		
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
<b>Total Revenues</b>	<b>758,761</b>	<b>758,217</b>
<b>Expenses:</b>		
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
<b>Total Expenses</b>	<b>840,459</b>	<b>923,762</b>
<b>Operating Loss</b>	<b>(81,698)</b>	<b>(165,545)</b>
<b>Other Income (Expense), net:</b>		
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)
<b>Total Other Income (Expense), net</b>	<b>26,807</b>	<b>(28,954)</b>
<b>Loss Before Income Taxes</b>	<b>(54,891)</b>	<b>(194,499)</b>
<b>Provision (Benefit) for Income Taxes</b>	<b>13,328</b>	<b>(3,233)</b>
<b>Net Loss — GAAP</b>	<b>\$ (68,219)</b>	<b>\$ (191,266)</b>
<b>(Loss) Earnings Per Share:</b>		
GAAP loss per share — basic and diluted	\$ (0.43)	\$ (1.22)
Non-GAAP earnings (loss) per share — basic and diluted	\$ 0.33	\$ (0.12)
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
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:		
<b>Net Loss — GAAP</b>	\$ (68,219)	\$ (191,266)
<b>Adjustments:</b>		
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)
<b>Non-GAAP Net Income (Loss)</b>	<b>\$ 52,103</b>	<b>\$ (19,206)</b>

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

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
<b>Total Assets</b>	<b>\$ 1,876,820</b>	<b>\$ 1,805,403</b>
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
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,876,820</b>	<b>\$ 1,805,403</b>
Ordinary shares outstanding (in thousands)	159,105	157,779

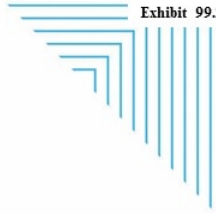
This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, which the company intends to file in October 2020.

**Alkermes plc and Subsidiaries**  
**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:

<u>(In millions, except per share data)</u>	<u>Amount</u>	<u>Shares</u>	<u>(Loss) Earnings Per Share</u>
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.



# Third Quarter 2020 Financial Results & Business Update

October 29, 2020



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# Forward-Looking Statements and Non-GAAP Financial Information

Certain statements set forth in this presentation 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 with respect to its future financial and operating performance, business plans or prospects; the potential therapeutic and commercial value of the company’s marketed and development products; the company’s expectations and assumptions regarding the future impacts of COVID-19 on its business; the company’s expectations concerning future regulatory activities and interactions, including expected timing of the U.S. Food and Drug Administration’s (“FDA”) target Prescription Drug User Fee Act (“PDUFA”) action date for the new drug application (“NDA”) for ALKS 3831 and, if approved, Drug Enforcement Administration de-scheduling of ALKS 3831; the company’s expectations concerning future development activities, including with respect to the ongoing ARTISTRY clinical development program and plans to present data from the program at a medical meeting; the company’s expectations concerning its commercial activities and capabilities, including launch planning strategies and activities for the potential launch of ALKS 3831. The company cautions that forward-looking statements are inherently uncertain. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks, assumptions and uncertainties. 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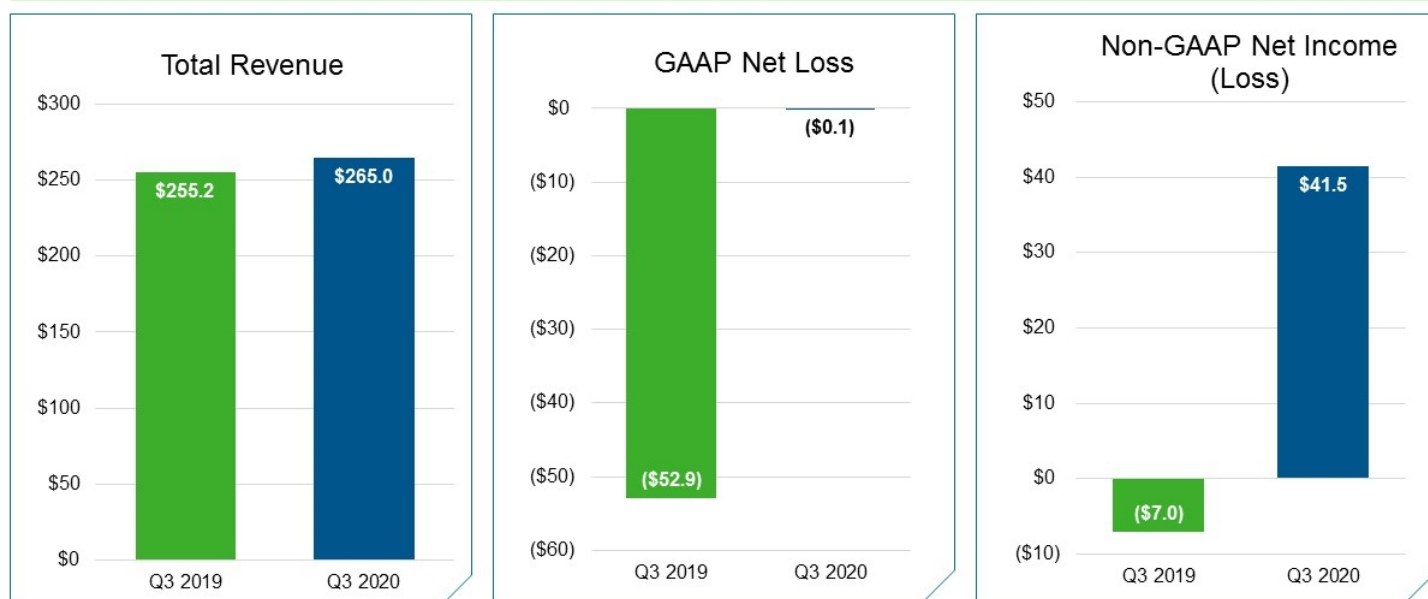


# Agenda

- **Introduction**  
Sandy Coombs, VP, Investor Relations
- **Q3 2020 Financial Results; 2020 Financial Expectations**  
Jim Frates, Chief Financial Officer
- **Q3 2020 Commercial Review**  
Todd Nichols, Chief Commercial Officer
- **R&D Pipeline and Business Update**  
Richard Pops, Chief Executive Officer



## Third Quarter 2020 Financial Results Summary



In millions

**Alkermes**

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## Third Quarter 2020 Revenue Summary

<i>In millions, except %</i>	Q3'20	Q3'19	$\Delta$ Q3'20 vs. Q3'19
VIVITROL®	\$80.3	\$85.2	(6%)
ARISTADA®	\$62.4	\$53.6	16%
Manufacturing & Royalty Revenue	\$120.4	\$103.8	16%
R&D and License Revenues	\$2.0	\$12.7	(84%)*
Total Revenue	\$265.0	\$255.2	4%

\* R&D revenues related to reimbursement for VUMERITY® development expenses largely concluded in Q4'19 following FDA approval

Amounts in the table above do not sum due to rounding.

## Alkermes: 2020 Financial Expectations<sup>†\*</sup>

<i>(in millions, except per share amounts)</i>	<b>Financial Expectations for Year Ending Dec. 31, 2020</b>
Revenues	\$1,010 – \$1,035
COGS	\$180 – \$190
R&D Expense	\$375 – \$390
SG&A Expense	\$530 – \$545
Amortization of Intangible Assets	~\$40
Other Income, Net	~\$30
Income Tax Expense	\$10 – \$15
GAAP Net Loss	(\$95) – (\$115)
GAAP Net Loss Per Share	(\$0.60) – (\$0.72)
Non-GAAP Net Income <sup>‡</sup>	\$50 – \$70
Non-GAAP Earnings Per Share (Diluted)	\$0.31 – \$0.43

Expected net sales of proprietary products:

- VIVITROL<sup>®</sup> net sales of \$305M – \$315M
- ARISTADA<sup>®</sup> net sales of \$230M – \$240M

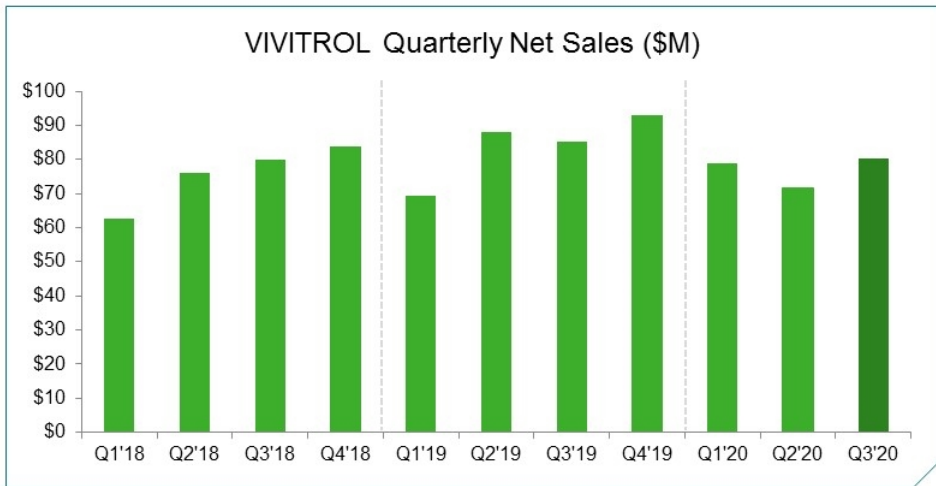
<sup>†</sup> These expectations are provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Oct. 29, 2020 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides financial expectations in a Regulation FD compliant manner.

<sup>\*</sup> Ranges provided are based on recent trends and assume that treatment provider practices and patient flow will continue to normalize. Additional COVID-19-related restrictions or resurgence of COVID-19 could negatively impact the Company's ability to meet these expectations.

<sup>‡</sup> Non-GAAP net income adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization expense; depreciation expense; non-cash net interest expense; change in the fair value of warrants; the income tax effect of these reconciling items; and certain other one-time or non-cash items. Reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure can be found in the Company's Current Report on Form 8-K filed with the SEC on Oct. 29, 2020.



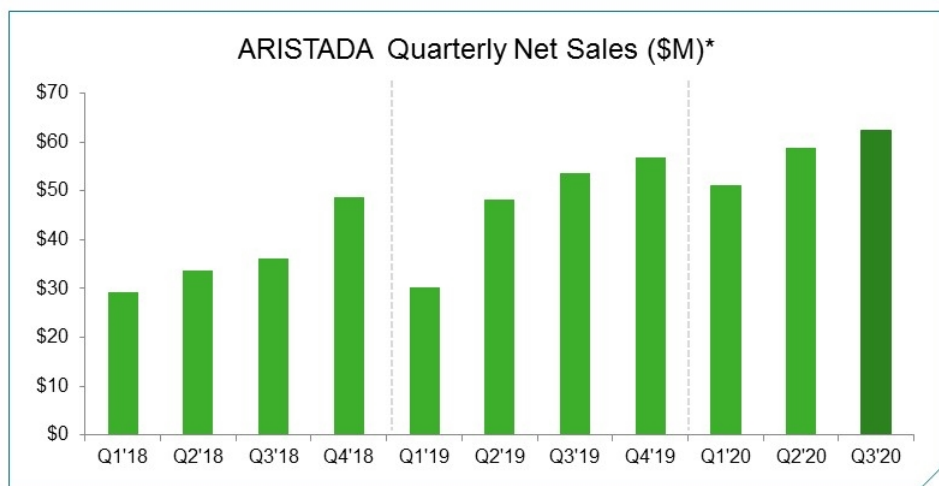
## VIVITROL® Performance



\*These expectations are provided by the Company in its Current Report on Form 8-K filed with the SEC on Oct. 29, 2020 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides financial expectations in a Regulation FD compliant manner.

- Q3 year-over-year net sales decline of **6%** to \$80.3M, driven by unit decline of **3%**
  - Sequential net sales increased 12% driven by unit growth of 22%
  - Gross-to-net deductions: 53% in Q3'20, compared to 49% in Q3'19 and 46% in Q2'20
  - Inventory levels rebounded by ~6,500 units in Q3'20 to a normal range
  - Expect gross-to-net adjustments in Q4'20 to increase to 54%, driven by expected increased Medicaid utilization\*

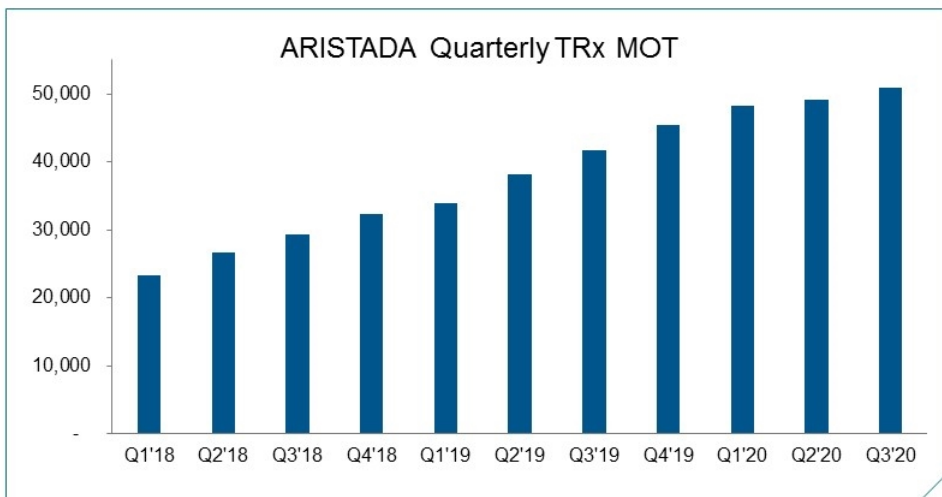
## ARISTADA® Performance



- Q3 year-over-year net sales growth of **16%** to \$62.4M, driven by unit growth of **20%**
  - Gross-to-net deductions: 54% in Q3'20, compared to 48% in Q3'19 and 53% in Q2'20
  - Increased gross-to-net adjustments in Q3'20 reflect increased Medicaid utilization
- Inventory levels increased ~1,900 units; within normal levels at 9/30/20

\*Inclusive of ARISTADA INITIO®

## ARISTADA®: Prescription Growth Trends



- Q3 year-over-year **growth of 22%** on TRx months of therapy (MOT) basis
  - Outpaced overall atypical long-acting injectable (LAI) market Q3 year-over-year growth of 5%
- Market share:
  - TRx MOT: **9%** of atypical LAI market prescriptions in August 2020
- Utilization of two-month dose drove **37%** of ARISTADA Q3'20 volume in terms of MOT

Source: IMS NPA

# ALKS 3831 Update

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## Regulatory Review

- Positive outcome of Advisory Committee meeting
  - Prescription Drug User Fee Act (PDUFA) target action date of Nov. 15, 2020
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## Launch Planning Activities

- Payer engagement strategy
  - Expect that access will improve throughout first year of launch as formulary decisions are made
  - Plan to implement patient access programs designed to mitigate payer restrictions early in launch
- Sales force planning
  - Focus on leveraging existing commercial organization
  - Hybrid promotional model permanently incorporates both in-person and virtual engagements to efficiently target a broader footprint of prescribers for oral antipsychotics
- Well-defined healthcare provider call universe
  - Plan to target healthcare providers that represent ~ 70% of the oral antipsychotic market, and ~ 80% of the branded oral antipsychotic market
- Commercial launch pending FDA approval and DEA de-scheduling

## ALKS 4230: Advancing the Clinical Development Program

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- ARTISTRY-1 data presented at the European Society for Medical Oncology (ESMO) Virtual Congress included evidence of ALKS 4230 antitumor activity, both as monotherapy and in combination with pembrolizumab, with durable and deepening responses observed in a diverse set of difficult-to-treat tumor types
- ARTISTRY-2 dose escalation is ongoing for both once-weekly and once-every-three-week subcutaneous dosing regimens
  - Data to be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November will include pharmacokinetic, pharmacodynamic, safety and tolerability data from the initial dose escalation cohorts



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