

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 18, 2019

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 23, 2019, Alkermes plc (the “Company”) announced financial results for the three and nine months ended September 30, 2019, updated certain financial expectations for the year ending December 31, 2019 and announced implementation of a restructuring. A copy of the related press release is furnished hereto as Exhibit 99.1. A copy of the investor presentation, to be displayed during the Company’s conference call on October 23, 2019, discussing financial results for the three and nine months ended September 30, 2019 and financial expectations for the year ending December 31, 2019, and providing an update on the business, is furnished hereto as Exhibit 99.2. 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 (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 2.05 Costs Associated with Exit or Disposal Activities.

Following a review of the Company’s operations, cost structure and growth opportunities, on October 18, 2019, the Board of Directors of the Company approved a plan of restructuring, which includes the elimination of approximately 160 current positions across the Company and other cost-saving measures (the “Restructuring”). The Company expects to substantially complete the workforce reduction by the end of 2019, with any remaining positions expected to be eliminated by mid-2020.

The Company has offered one-time termination benefits to the affected employees, including cash severance payments, healthcare benefits, and outplacement assistance. Each affected employee’s eligibility for these termination benefits is contingent upon such employee’s execution (and non-revocation) of a separation agreement with the Company containing a general release of claims against the Company.

The Company expects to record a charge in the range of \$13.0 million to \$15.0 million in the fourth quarter of 2019 as a result of the Restructuring, consisting of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out over the next 12 months. The Company’s estimates are based on a number of assumptions. Actual results may differ materially and additional charges not currently expected may be incurred in connection with, or as a result of, the Restructuring.

Note Regarding Forward-Looking Statements

Certain statements set forth in Item 2.05 above constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, including, but not limited to, statements concerning: the Company’s expectations relating to the Restructuring, including the anticipated workforce reductions, timing of completion of the Restructuring, and timing and amounts of the charge to be recorded and cash expenditures to be made in connection with the Restructuring. The Company cautions that forward-looking statements are inherently uncertain. Although the Company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, 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: the Company’s ability to complete the Restructuring within the anticipated timeline; the impact of the workforce reduction on the Company’s business; unanticipated charges not currently contemplated that may occur as a result of the Restructuring; and those risks and uncertainties described in the Company’s Annual Report on Form 10-K for the year ended Dec. 31, 2018, 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 Item 2.05 above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Alkermes plc dated October 23, 2019 announcing financial results for the three and nine months ended September 30, 2019 and financial expectations for the year ending December 31, 2019.
99.2	Investor presentation to be displayed by Alkermes plc on October 23, 2019.
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 23, 2019

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

Alkermes Contacts:

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Alkermes Plc Reports Third Quarter 2019 Financial Results and Implementation of Restructuring

— *Third Quarter Revenues of \$255.2 Million, Primarily Driven by Approximately 20% Year-Over-Year Growth of Proprietary Product Net Sales* —

— *Company Reports GAAP Net Loss per Share of \$0.34 and Non-GAAP Net Loss per Share of \$0.04* —

— *Restructuring Significantly Decreases Operating Expense Base and is Expected to Deliver Cost Savings of Several Hundred Million Dollars Over the Next Few Years* —

— *Company Updates Financial Expectations for 2019* —

DUBLIN, Ireland, Oct. 23, 2019 — Alkermes plc (Nasdaq: ALKS) today reported financial results for the third quarter of 2019 and the implementation of a restructuring plan following a review of the company's operations, cost structure and growth opportunities.

"As the profile of Alkermes changes, our executional priorities are clear: maximize the value of our commercial products and development candidates, streamline our cost structure and position the company for sustained future profitability. The restructuring is designed to further focus our R&D efforts on specific high-potential programs within CNS and oncology, improve financial efficiencies in our SG&A organization and drive growth," commented Richard Pops, Chief Executive Officer of Alkermes. "VIVITROL® and ARISTADA® provide a strong and growing foundation for our commercial business and the anticipated commercial launch of VUMERITY™ will provide a profitable new source of royalty revenues. We also continue to advance our pipeline programs, with the planned submission of the ALKS 3831 New Drug Application for both schizophrenia and bipolar I disorder this quarter, and the planned presentation of new data from ALKS 4230, our phase 1/2 immuno-oncology asset, at an upcoming medical meeting."

Quarter Ended Sept. 30, 2019 Financial Highlights

- Total revenues for the quarter were \$255.2 million, compared to \$248.7 million for the same period in the prior year, primarily driven by approximately 20% growth in net sales of our proprietary products, partially offset by a decrease in AMPYRA®ⁱ revenues resulting from generic entry in 2018.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$52.9 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.34. This compared to GAAP net loss of \$34.4 million, or a basic and diluted GAAP net loss per share of \$0.22, for the same period in the prior year.
- Non-GAAP net loss was \$7.0 million for the quarter, or a non-GAAP basic and diluted net loss per share of \$0.04. This compared to non-GAAP net income of \$11.6 million, or a non-GAAP basic and diluted net earnings per share of \$0.07, for the same period in the prior year.

Quarter Ended Sept. 30, 2019 Financial Results**Revenues**

- Net sales of VIVITROL were \$85.2 million, compared to \$79.9 million for the same period in the prior year, representing an increase of approximately 7%.
 - Net sales of ARISTADAⁱⁱ were \$53.6 million, compared to \$36.1 million for the same period in the prior year, representing an increase of approximately 48%.
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- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$76.7 million, compared to \$77.2 million for the same period in the prior year, reflecting lower manufacturing revenues from RISPERDAL CONSTA.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA® were \$7.7 million, compared to \$20.3 million for the same period in the prior year, due to generic competition to AMPYRA entering the market in 2018 in the U.S.
- Research and development revenues were \$12.7 million, compared to \$16.3 million for the same period in the prior year. These revenues were primarily related to the collaboration with Biogen for VUMERITY.

Costs and Expenses

- Operating expenses were \$308.9 million, compared to \$285.9 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA and in the development of ALKS 4230.

“Our third quarter results reflect solid year-over-year growth of VIVITROL and ARISTADA. We are committed to further improving our financial efficiency and focusing the investments we are making to support our future growth,” commented James Frates, Chief Financial Officer of Alkermes. “As we approach the end of the year, we are refining our financial expectations for 2019, including an increase in our expectations for non-GAAP net income, to reflect our results year-to-date, expectations for the fourth quarter and the impact of the restructuring announced today.”

Restructuring

In October 2019, Alkermes completed a review of the company’s operations, cost structure and growth opportunities and implemented a restructuring plan. The restructuring included the elimination of approximately 160 current positions across the organization, a decrease in the company’s expected near-term hiring plans and implementation of cost-saving measures related to external spend. These efforts are expected to result in cost savings of approximately \$150 million. The company expects to record a charge of approximately \$15 million in the fourth quarter of 2019 as a result of the restructuring, consisting of one-time termination benefits for employee severance, benefits and related costs.

Financial Expectations for 2019

The following outlines the company’s updated financial expectations for 2019, which include the impact of the restructuring announced today:

- **Revenues:** The company continues to expect total revenues to range from \$1.14 billion to \$1.19 billion.
 - Included in this total revenue expectation is the \$150 million milestone payment that will be triggered by final approval of VUMERITY by the U.S. Food and Drug Administration (FDA).
 - The company now expects VIVITROL net sales to range from \$330 million to \$340 million, revised from the prior expectation of \$330 million to \$350 million.
 - The company now expects ARISTADA net sales to range from \$185 million to \$190 million, revised from the prior expectation of \$200 million to \$210 million.
- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from \$180 million to \$190 million.

- **Research and Development (R&D) Expenses:** The company now expects R&D expenses to range from \$430 million to \$450 million, revised from the prior expectation of \$450 million to \$480 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company now expects SG&A expenses to range from \$590 million to \$610 million, revised from the prior expectation of \$590 million to \$620 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangible assets to be approximately \$40 million.
- **Restructuring:** The company expects a restructuring charge of approximately \$15 million.
- **Net Interest Expense:** The company now expects net interest expense to range from \$0 to \$5 million, revised from the prior expectation of \$5 million to \$10 million.
- **Other Income/Expense, Net:** The company expects a net other expense of approximately \$30 million related to the change in fair value of its contingent consideration.
- **Income Tax Expense:** The company now expects income tax expense to range from \$0 to \$5 million, revised from the prior expectation of \$10 million to \$15 million.
- **GAAP Net Loss:** The company continues to expect GAAP net loss to range from \$135 million to \$165 million, or a basic and diluted loss per share of \$0.86 to \$1.05, based on a weighted average basic and diluted share count of approximately 156 million shares outstanding.
- **Non-GAAP Net Income:** The company now expects non-GAAP net income to range from \$70 million to \$90 million, or a non-GAAP basic earnings per share of \$0.45 to \$0.57, based on a weighted average basic share count of approximately 157 million shares outstanding and a non-GAAP diluted earnings per share of \$0.44 to \$0.57, based on a weighted average diluted share count of approximately 159 million shares outstanding. This compares to the previous expectation of non-GAAP net income in the range of \$40 million to \$70 million, or a non-GAAP basic earnings per share of \$0.26 to \$0.45, based on a weighted average basic share count of approximately 156 million shares outstanding and a non-GAAP diluted earnings per share of \$0.25 to \$0.43, based on a weighted average diluted share count of approximately 161 million shares outstanding.
- **Share-Based Compensation:** The company now expects share-based compensation of approximately \$100 million, revised from the prior expectation of approximately \$120 million.
- **Capital Expenditures:** The company now expects capital expenditures to range from \$80 million to \$90 million, revised from the prior expectation of \$90 million to \$100 million.

Recent Events:

- Entered into clinical collaboration with Fred Hutchinson Cancer Research Center for a planned phase 2 multi-site trial to evaluate ALKS 4230 in combination with pembrolizumab in patients with advanced or recurrent head and neck squamous cell cancer.
- Received tentative approval from FDA for VUMERITY (dioximel fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of MS.
- Presented new health economics and outcomes research at the 32nd Annual Psych Congress that highlighted the unmet needs of individuals living with schizophrenia and bipolar I disorder in real-world settings.
- Announced the appointment of Richard Gaynor, M.D. and Andy Wilson to the company's Board of Directors. Dr. Gaynor brings to the Board 18 years of experience in oncology-focused drug development, and Mr. Wilson brings to the Board 30 years of financial expertise and experience in strategic planning and business development. The company also announced the retirement of Floyd Bloom, M.D., a founder of Alkermes, Inc., from the Board.

- Announced positive topline results from EVOLVE-MS-2, a phase 3 study designed to evaluate the gastrointestinal (GI) tolerability of VUMERITY compared to TECFIDERA® in patients with relapsing-remitting multiple sclerosis.
- Entered into a settlement and license agreement with Amneal Pharmaceuticals LLC (Amneal) to resolve Amneal's *inter partes* review petition challenging U.S. Patent Number 7,919,499, an Orange Book-listed patent for VIVITROL.

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, Oct. 23, 2019, to discuss these financial results 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 (4:00 p.m. BST) on Wednesday, Oct. 23, 2019, through Wednesday, Oct. 30, 2019, 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 access code is 13694597.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for diseases that include schizophrenia, depression, addiction, multiple sclerosis, 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 net 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; certain other one-time or non-cash items; changes in the fair value of contingent consideration; changes in the fair value of warrants and equity method investments; restructuring charges; and the income tax effect of these reconciling items.

The company's management and board of directors 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 net 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 net earnings (loss) per share should not be considered measures of our liquidity.

A reconciliation of certain 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 business plans or prospects; the company’s expectations concerning future financial and operating performance, including the potential cost savings that may be achieved in connection with the company’s implementation of a restructuring, and the company’s potential future profitability and continued growth, including expectations of continued revenue growth from the company’s commercial products and royalty streams and the potential addition of VUMERITY as a new source of royalty revenue; expectations concerning the company’s continued investment in its development pipeline and commercial products and capabilities, and the value that can be derived therefrom; the potential therapeutic and commercial value of the company’s marketed and development products; expectations concerning the timing, details and results of the company’s clinical development activities, including plans for the presentation of new data for ALKS 4230 at an upcoming medical meeting; the company’s expectations and timelines for regulatory activities and interactions with the FDA, including the company’s planned submission of an NDA for ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder; and the company’s expectations relating to the anticipated launch of VUMERITY and the financial benefits that may be achieved under the company’s license and collaboration agreement with Biogen. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, 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: that the expected cost savings related to the company’s implementation of a restructuring plan may not be achieved or may be lower than anticipated; the unfavorable outcome of litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to any of our products or products using our proprietary technologies, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and adequacy of the data included to support the proposed indications; clinical development activities may not be completed on time or at all; the results of our 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 or approved in a timely manner; 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 FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company’s products; 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 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.

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland Limited and VUMERITY™ is a trademark of Alkermes Pharma Ireland Limited used by Biogen under an exclusive license; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; and AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.

(tables follow)

ⁱ AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda. Biogen Inc. markets this product as FAMPYRA® (prolonged-release fampridine tablets) outside the U.S. under a licensing agreement with Acorda.

ⁱⁱ 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, 2019	Three Months Ended September 30, 2018
Revenues:		
Product sales, net	\$ 138,774	\$ 116,035
Manufacturing and royalty revenues	103,783	116,411
Research and development revenue	12,686	16,274
Total Revenues	255,243	248,720
Expenses:		
Cost of goods manufactured and sold	42,319	39,410
Research and development	107,671	101,265
Selling, general and administrative	148,701	128,777
Amortization of acquired intangible assets	10,173	16,426
Total Expenses	308,864	285,878
Operating Loss	(53,621)	(37,158)
Other (Expense) Income, net:		
Interest income	3,509	2,561
Interest expense	(3,385)	(3,346)
Change in the fair value of contingent consideration	1,300	4,200
Other expense, net	(1,664)	(90)
Total Other (Expense) Income, net	(240)	3,325
Loss Before Income Taxes	(53,861)	(33,833)
(Benefit) Provision for Income Taxes	(983)	611
Net Loss — GAAP	\$ (52,878)	\$ (34,444)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	\$ (0.34)	\$ (0.22)
Non-GAAP net (loss) earnings per share — basic and diluted	\$ (0.04)	\$ 0.07
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	157,199	155,328
Basic — Non-GAAP	157,199	155,328
Diluted — Non-GAAP	157,199	159,763
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net (loss) income is as follows:		
Net Loss — GAAP	\$ (52,878)	\$ (34,444)
Adjustments:		
Share-based compensation expense	26,729	25,068
Amortization expense	10,173	16,426
Depreciation expense	10,173	9,842
Change in the fair value of contingent consideration	(1,300)	(4,200)
Income tax effect related to reconciling items	155	(869)
Non-cash net interest expense	168	170
Change in the fair value of warrants and equity method investments	(206)	(367)
Non-GAAP Net (Loss) Income	\$ (6,986)	\$ 11,626

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, 2019	Nine Months Ended September 30, 2018
Revenues:		
Product sales, net	\$ 374,890	\$ 317,684
Manufacturing and royalty revenues	340,595	359,253
Research and development revenue	41,732	53,325
License revenue	1,000	48,250
Total Revenues	<u>758,217</u>	<u>778,512</u>
Expenses:		
Cost of goods manufactured and sold	133,903	127,303
Research and development	314,676	316,434
Selling, general and administrative	444,996	385,181
Amortization of acquired intangible assets	30,187	48,742
Total Expenses	<u>923,762</u>	<u>877,660</u>
Operating Loss	<u>(165,545)</u>	<u>(99,148)</u>
Other Expense, net:		
Interest income	10,785	5,946
Interest expense	(10,405)	(11,959)
Change in the fair value of contingent consideration	(27,800)	(17,300)
Other expense, net	(1,534)	(2,815)
Total Other Expense, net	<u>(28,954)</u>	<u>(26,128)</u>
Loss Before Income Taxes	<u>(194,499)</u>	<u>(125,276)</u>
(Benefit) Provision for Income Taxes	<u>(3,233)</u>	<u>4,322</u>
Net Loss — GAAP	<u>\$ (191,266)</u>	<u>\$ (129,598)</u>
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	\$ (1.22)	\$ (0.84)
Non-GAAP net (loss) earnings per share — basic	\$ (0.12)	\$ 0.28
Non-GAAP net (loss) earnings per share — diluted	\$ (0.12)	\$ 0.27
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	156,845	154,979
Basic — Non-GAAP	<u>156,845</u>	<u>154,979</u>
Diluted — Non-GAAP	<u>156,845</u>	<u>160,224</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net (loss) income is as follows:		
Net Loss — GAAP	\$ (191,266)	\$ (129,598)
Adjustments:		
Share-based compensation expense	79,590	76,043
Amortization expense	30,187	48,742
Depreciation expense	29,715	29,016
Change in the fair value of contingent consideration	27,800	17,300
Income tax effect related to reconciling items	5,170	(5,535)
Non-cash net interest expense	505	531
Change in the fair value of warrants and equity method investments	(907)	600
Restructuring expense	—	3,598
Debt refinancing charge	—	2,298
Non-GAAP Net (Loss) Income	<u>\$ (19,206)</u>	<u>\$ 42,995</u>

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	September 30, 2019	December 31, 2018
Cash, cash equivalents and total investments	\$ 608,533	\$ 620,039
Receivables	250,234	292,223
Contract assets	5,022	8,230
Inventory	100,987	90,196
Prepaid expenses and other current assets	54,493	53,308
Property, plant and equipment, net	341,406	309,987
Intangible assets, net and goodwill	253,687	283,874
Other assets	143,633	167,150
Total Assets	\$ 1,757,995	\$ 1,825,007
Long-term debt — current portion	2,843	2,843
Other current liabilities	367,551	336,931
Long-term debt	274,838	276,465
Contract liabilities — long-term	11,188	9,525
Other long-term liabilities	33,391	27,958
Total shareholders' equity	1,068,184	1,171,285
Total Liabilities and Shareholders' Equity	\$ 1,757,995	\$ 1,825,007
Ordinary shares outstanding (in thousands)	157,476	155,757

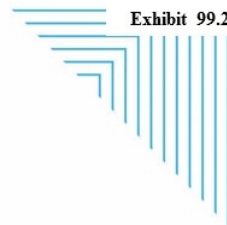
This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2019, which the company intends to file in October 2019.

Alkermes plc and Subsidiaries
2019 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:

(In millions, except per share data)	Amount	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	\$ (150.0)	157	\$ (0.96)
Adjustments:			
Share-based compensation expense	100.0		
Amortization expense	40.0		
Depreciation expense	40.0		
Change in the fair value of contingent consideration	30.0		
Restructuring	15.0		
Income tax effect related to reconciling items	4.0		
Non-cash net interest expense	1.0		
Projected Net Income — Non-GAAP	\$ 80.0	159	\$ 0.50

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



Third Quarter 2019 Financial Results & Business Update

October 23, 2019



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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, including the potential cost savings that may be achieved in connection with the company’s implementation of a restructuring; expectations with respect to continued revenue growth from the company’s commercial products, manufacturing activities and royalty streams; the expected addition of VUMERITY™ to the portfolio of royalty streams, the therapeutic and commercial value of the company’s marketed and development products; expectations concerning the timing, results and momentum of clinical development activities relating to the company’s products and product development candidates, including the presentation of data for ALKS 4230 and ongoing activities in the ARTISTRY program for ALKS 4230; the company’s expectations and timelines for regulatory interactions with, and actions by, the U.S. Food and Drug Administration (“FDA”) including expected timing for the FDA’s approval of VUMERITY and the company’s planned new drug application (“NDA”) submission for ALKS 3831, the expected data to be contained in such NDA for ALKS 3831 and the adequacy of such data to serve as the basis of an NDA for ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder; the potential financial benefits that may be achieved under the license and collaboration agreement between the company and Biogen for VUMERITY, including receipt from Biogen of the approval milestone payment; and expectations concerning the timing and results of commercial activities relating to the company’s products, including the expected launch of VUMERITY. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, 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, assumptions and uncertainties include, among others: that the expected annual cost savings related to the company’s implementation of a restructuring may not be achieved or may be lower than anticipated; the unfavorable outcome of litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to any of the company’s products, which may lead to competition from generic drug manufacturers; 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 the company’s filings for its products, including its clinical trial designs, conduct and methodologies or the sufficiency of the results thereof to support approval; 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, preliminary or interim results in the company’s clinical trials may not be predictive of final results of such clinical trials, results of future clinical trials or real-world results; regulatory submissions may not occur or be submitted or approved in a timely manner; 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 FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company’s products; 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; the potential financial, commercial and therapeutic benefits of collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen may not be achieved; and those risks, assumptions and uncertainties described under the heading “Risk Factors” in the company’s most recent Annual Report on Form 10-K 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, and on the company’s website at www.alkermes.com in the “Investors – SEC filings” section. 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 presentation.

Non-GAAP Financial Measures: This presentation includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income and non-GAAP earnings 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. Reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Alkermes plc Current Report on Form 8-K filed with the SEC on Oct. 23, 2019.

Note Regarding Trademarks: The company is the owner of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA®, ARISTADA INITIO®, VIVITROL® and VUMERITY™. Any other trademarks referred to in this presentation are the property of their respective owners. Appearances of such other trademarks herein should not be construed as any indicator that their respective owners will not assert their rights thereto.



Third Quarter Earnings Call Agenda

Introduction

Richard Pops, Chief Executive Officer

Q3 2019 Financial Results

Jim Frates, Chief Financial Officer

Business Update

Richard Pops, Chief Executive Officer



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Implementation of Restructuring

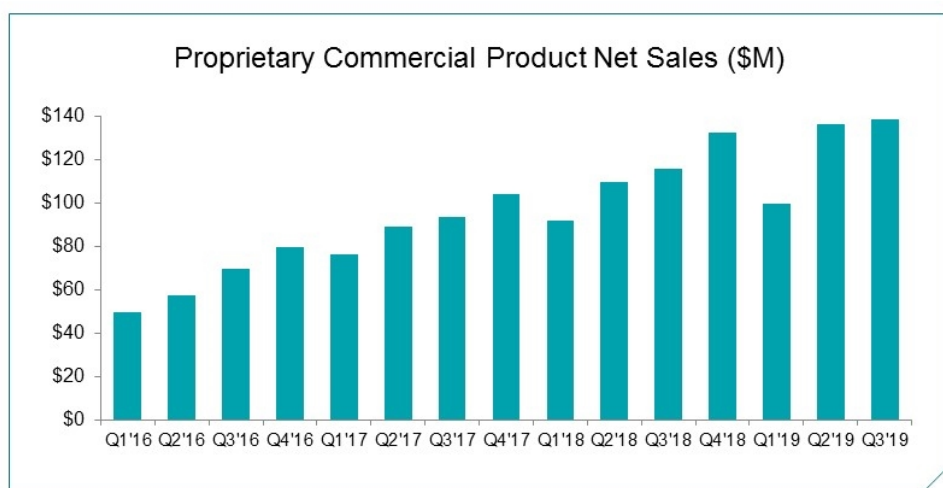
- Follows comprehensive review of topline growth, cost structure and operations
- Expected to yield cost savings of \$150M, including:
 - Workforce reduction – elimination of approximately 160 current positions
 - Recalibrated future hiring plans
 - Substantially decreased external spend
- Re-baselines expense profile; Expected to deliver total cost savings of several hundred million dollars over next few years
- Improved financial efficiency will help us achieve three key objectives:
 - Sustained non-GAAP profitability
 - Increased flexibility to pursue business development opportunities
 - Preserved ability to invest appropriately in ALKS 4230 and preparations for potential launch of ALKS 3831

Third Quarter 2019 Revenue Summary

<i>In millions, except %</i>	Q3'19	Q3'18	Δ Q3'19 vs. Q3'18
VIVITROL®	\$85.2	\$79.9	7%
ARISTADA®	\$53.6	\$36.1	48%
Manufacturing & Royalty Revenue	\$103.8*	\$116.4	(11)%
R&D Revenue	\$12.7	\$16.3	(22)%
Total Revenue	\$255.2*	\$248.7	3%

*These results reflect a \$12.6 million decline in revenues from the AMPYRA®/FAMPYRA® franchise compared to the prior year, following generic competition to AMPYRA entering the U.S. market in 2018.

Net Sales From Proprietary Commercial Medicines



**ARISTADA
INITIO[®]**
aripiprazole lauroxil
extended-release injectable suspension

675 mg

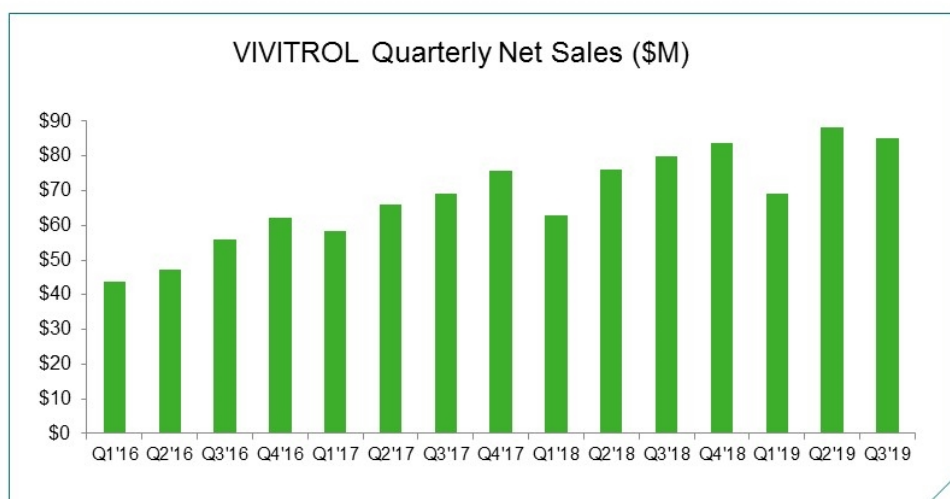
+

ARISTADA[®]
aripiprazole lauroxil
extended-release injectable suspension

441 mg 662 mg 882 mg 1064 mg

Vivitrol[®]
(naltrexone for extended-release
injectable suspension)

VIVITROL® Performance and Expectations



- ▶ Q3 year-over-year net sales growth of **7%** to \$85.2M, driven by underlying unit growth of **11%**
 - Sequential decrease primarily driven by fluctuations in gross-to-net adjustments that favorably impacted Q2'19 net sales by ~\$3M
 - Gross-to-net deductions of 49% in Q3'19, compared to 48% in Q2'19 and 47% in Q3'18
- ▶ 2019 full year net sales now expected to range from **\$330M - \$340M[†]**

[†]This guidance is provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Oct. 23, 2019 and is effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance and only provides guidance in a Regulation FD compliant manner.

ARISTADA® Performance and Expectations



- Q3 year-over-year net sales growth of **48%** to \$53.6M, driven by underlying unit growth of **42%**
 - Gross-to-net deductions of 48%, compared to 48% in Q2'19 and 47% in Q3'18
- Q3 prescriptions increased by 9% sequentially and 42% year-over-year, on a TRx months of therapy (MOT) basis¹
- 2019 full year net sales now expected to range from **\$185M - \$190M[†]**

1. IMS NPA

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Alkermes: 2019 Financial Expectations

<i>(in millions, except per share amounts)</i>	Revised Financial Expectations for Year Ending Dec. 31, 2019[†]
Revenues	\$1,140 – 1,190
COGS	\$180 – 190
R&D Expense	\$430 – 450
SG&A Expense	\$590 – 610
Amortization of Intangible Assets	~\$40
Net Interest Expense	\$0 to \$5
Income Tax Expense	\$0 to \$5
Other Income/Expense, Net	~\$30
Restructuring Expense	~\$15
GAAP Net Loss	\$(135) – (165)
GAAP Net Loss Per Share	\$(0.86) – (1.05)
Non-GAAP Net Income [‡]	\$70 – 90
Non-GAAP Earnings Per Share (Basic)	\$0.45 – 0.57
Non-GAAP Earnings Per Share (Diluted)	\$0.44 – 0.57

Revenues[†]:

- VIVITROL[®] net sales of \$330M - \$340M
- ARISTADA[®] net sales of \$185M - \$190M
- License revenues: \$150M milestone anticipated upon FDA approval of diroximel fumarate (expected Q4'19)

[†] This guidance is provided by the Company in its Current Report on Form 8-K filed with the SEC on Oct. 23, 2019 and is effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm this guidance. The Company only provides guidance in a Regulation FD compliant manner.

[‡] Non-GAAP net income adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; change in the fair value of contingent consideration; change in the fair value of warrants and equity method investments; and the income tax effect of these reconciling 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. 23, 2019.



Royalty and Manufacturing Business

- Partnered long-acting injectables: Meaningful revenues expected into the mid-2020s
- VUMERITY™: Expected launch will add to portfolio of royalty revenue streams
 - Announced FDA tentative approval of VUMERITY
 - FDA final approval will trigger \$150 milestone payment from Biogen
 - Alkermes to receive mid-teens royalty on net sales
 - Positive topline results from EVOLVE-MS-2, a phase 3 study designed to evaluate the gastrointestinal (GI) tolerability of VUMERITY compared to TECFIDERA® in patients with relapsing-remitting multiple sclerosis, announced in July 2019
 - VUMERITY demonstrated statistically superior gastrointestinal tolerability compared to TECFIDERA on the study's primary endpoint assessing self-reported GI events and a discontinuation rate of less than 1% due to GI adverse events
 - The most common adverse events reported in the study for both treatment groups were flushing, diarrhea and nausea

Proprietary Commercial Products

- VIVITROL net sales continued to be concentrated geographically, but we have seen more diversified growth
 - Top five states represented 43% of volume during Q3'19
 - Pennsylvania, Ohio, Massachusetts, New York, California
 - Diversified growth: In Q3'19, 22 states grew >25% year-over-year
- ARISTADA underlying prescription trends continued to demonstrate solid growth
 - On a TRx MOT basis, Q3 sequential growth was 9%, compared to the broader atypical long-acting injectable (aLAI) market growth of 3% sequentially¹
 - Year-over-year, Q3 ARISTADA TRx MOT grew 42%, compared to the broader aLAI market which grew 14% year-over-year¹
 - Market share:
 - 31% of new aripiprazole long-acting injectable (LAI) prescriptions (MOT) in September 2019, up from 28% in September 2018¹
 - 9% of overall LAI market in September 2019, up from 7% in September 2018¹

1. IMS NPA

Advancing Pipeline of Development Products

- ALKS 3831
 - Single 505(b)(2) NDA submission for treatment of schizophrenia and bipolar I disorder planned for Q4'19
- ALKS 4230
 - ARTISTRY-1 and ARTISTRY-2 clinical development programs underway
 - Data presentation planned for Society for Immunotherapy of Cancer Annual Meeting in November
 - Announced clinical collaboration with Fred Hutchinson Cancer Research Center for a planned phase 2 multi-site trial to evaluate ALKS 4230 in combination with pembrolizumab in patients with advanced or recurrent head and neck squamous cell cancer

News Flow Expected in 2019

Schizophrenia

ARISTADA®

- ✓ Report topline results for ALPINE phase 3b study (Q2)

ALKS 3831

- ✓ Present ENLIGHTEN-2 data at medical meeting (Q2)
- ☐ Submit single NDA for schizophrenia and bipolar I disorder (Q4)

Addiction

VIVITROL®

- ✓ Present and publish data on detox and induction strategies

Multiple Sclerosis

Diroximel fumarate

- ✓ Report topline data for EVOLVE-MS-2 head-to-head vs. TECFIDERA® (Q3)
- ☐ Expected FDA regulatory action (Q4)

Immuno-oncology

ALKS 4230

- ✓ Initiate monotherapy expansion stage of ARTISTRY-1 study (Q2)
- ☐ Presentation of data from ARTISTRY program at medical meeting (Q4)
- ✓ Initiate ARTISTRY-2 subcutaneous dosing study (Q1)

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