

**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): February 11, 2021

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 February 11, 2021, Alkermes plc (the “Company”) announced financial results for the three months and year ended December 31, 2020 and financial expectations for the year ending December 31, 2021. Copies of the related press release and the investor presentation to be displayed during the Company’s conference call on February 11, 2021 discussing such financial results and 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

Exhibit No.	Description
99.1	Press release issued by Alkermes plc dated February 11, 2021 announcing financial results for the three months and year ended December 31, 2020 and financial expectations for the year ending December 31, 2021.
99.2	Investor presentation to be displayed by Alkermes plc on February 11, 2021.
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.

Date: February 11, 2021

ALKERMES PLC

By: /s/ Iain M. Brown
Iain M. Brown
Senior Vice President, Chief Financial Officer (Principal
Financial Officer and Principal Accounting Officer)

Alkermes Contacts:

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 For Media: Katie Joyce +1 781 249 8927

Alkermes plc Reports Financial Results for the Fourth Quarter and Year Ended Dec. 31, 2020 and Provides Financial Expectations for 2021

—Revenues of \$1.04 Billion in 2020, GAAP Loss per Share of \$0.70 and Basic and Diluted Non-GAAP Earnings per Share of \$0.43—
 —Financial Expectations for 2021 Reflect Anticipated Growth of Proprietary Products and Investment in Strategic Priorities for Long-Term Value Creation—

DUBLIN, Feb. 11, 2021 — Alkermes plc (Nasdaq: ALKS) today reported financial results for the quarter and year ended Dec. 31, 2020 and provided financial expectations for 2021.

“2020 was a demonstration of the resiliency of our organization, as we adapted our business to endure a pandemic that has proved to be one of the most disruptive events in our recent history. Despite the challenges posed by COVID-19, we achieved significant growth of net sales from our portfolio of proprietary commercial products, advanced our pipeline of neuroscience and oncology candidates, and announced a Value Enhancement Plan designed to drive growth and improve operational and financial performance,” said Richard Pops, Chief Executive Officer of Alkermes. “We are focused on value creation in 2021 as we seek to grow and diversify our commercial portfolio, demonstrate the value of our R&D investments, and manage the company for growth and long-term profitability, all while striving to make a meaningful difference in the lives of people living with serious mental illness, addiction and cancer.”

Quarter Ended Dec. 31, 2020 Financial Highlights

- Total revenues for the quarter were \$280.0 million. This compared to \$412.7 million for the same period in the prior year, which included a \$150.0 million milestone payment from Biogen related to the U.S. Food and Drug Administration’s (FDA) approval of VUMERITY® in 2019.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$42.6 million for the quarter, or a basic and diluted GAAP loss per share of \$0.27. This compared to GAAP net loss of \$5.4 million, or a basic and diluted GAAP loss per share of \$0.03, for the same period in the prior year.
- Non-GAAP net income was \$16.5 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.10. This compared to non-GAAP net income of \$131.4 million, or a non-GAAP basic and diluted earnings per share of \$0.83 for the same period in the prior year.

Year Ended Dec. 31, 2020 Financial Results

Revenues

- Total revenues for the year were \$1.04 billion. This compared to \$1.17 billion in the prior year. Total revenues in 2019 included a \$150.0 million milestone payment from Biogen related to the FDA’s approval of VUMERITY, of which \$144.8 million was recorded as license revenue and \$5.2 million was recorded as research and development (R&D) revenue.
 - Net sales of proprietary products for the year were \$551.8 million, compared to \$524.5 million in the prior year.
 - Net sales of VIVITROL® were \$310.7 million, compared to \$335.4 million in the prior year, representing a decrease of approximately 7%, primarily due to COVID-19-pandemic-related disruptions.
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- Net sales of ARISTADA®1 were \$241.0 million, compared to \$189.1 million in the prior year, representing an increase of approximately 27%.
- Manufacturing and royalty revenues for the year were \$484.0 million, compared to \$447.9 million in the prior year.
 - Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$345.6 million, compared to \$323.3 million in the prior year.

Costs and Expenses

- Total operating expenses for the year were \$1.15 billion, compared to \$1.35 billion in the prior year.
 - R&D expenses were \$394.6 million, compared to \$512.8 million in the prior year, which included the \$86.6 million charge related to the acquisition of Rodin Therapeutics, Inc. (Rodin) in 2019.
 - Selling, General and Administrative (SG&A) expenses were \$538.8 million, compared to \$599.4 million in the prior year, primarily reflecting the impact of the restructuring implemented in 2019 and additional expense management measures in 2020.

Net Loss/Net Income

- GAAP net loss for the year was \$110.9 million, or a basic and diluted GAAP loss per share of \$0.70. This compared to GAAP net loss of \$196.6 million, or a basic and diluted GAAP loss per share of \$1.25, in the prior year.
- Non-GAAP net income for the year was \$68.6 million, or a non-GAAP basic and diluted earnings per share of \$0.43. This compared to non-GAAP net income of \$112.2 million, or a non-GAAP basic and diluted earnings per share of \$0.71, in the prior year, which included the \$150 million of revenue from Biogen following approval of VUMERITY.

Balance Sheet

- At Dec. 31, 2020, Alkermes recorded cash, cash equivalents and total investments of \$659.8 million, compared to \$597.2 million at Sept. 30, 2020, and \$614.4 million at Dec. 31, 2019, driven primarily by the company's operating results and changes in working capital. The company's total debt outstanding as of Dec. 31, 2020 was \$275.0 million, consisting of a term loan that matures in March 2023.

“Our solid 2020 financial results demonstrate efficient management of our business from a financial and operational perspective in response to the significant disruptions caused by the pandemic. These efforts underscore our focus on execution and reflect our commitment to driving bottom line growth,” commented Iain Brown, Chief Financial Officer of Alkermes. “We enter 2021 well positioned to execute on our strategic priorities and work toward the long-term profitability margin targets set forth in our Value Enhancement Plan. We plan to achieve these targets through commercial execution, focused investment in the company's future growth drivers and continued efforts to optimize our infrastructure and operating model. Our financial expectations for 2021 reflect anticipated growth of our commercial portfolio and focused investments to support the anticipated launch of LYBALVI™ and advance the clinical development program for nemvaleukin, as we position these programs to drive future value creation.”

Financial Expectations for 2021

The following financial expectations for 2021 are based on recent trends and assume continuation of such trends into the first half of the year, and an anticipated improvement in patient access to treatment providers and to the company's commercial products in the second half of the year. If patient access does not improve as anticipated, or if new COVID-19-related disruptions emerge, the company's ability to meet these expectations could be negatively impacted. All line items are according to GAAP, except as otherwise noted.

<i>In millions (except per share amounts)</i>	2021 Expectation <small>(Provided 2/11/21)</small>
Total Revenue	\$1,100 – \$1,170
VIVITROL Net Sales	\$315 – \$345
ARISTADA Net Sales	\$260 – \$290
LYBALVI Net Sales	<\$10
Cost of Goods Sold	\$190 – \$200
R&D Expenses	\$400 – \$430*
SG&A Expenses	\$570 – \$600
Amortization of Intangible Assets	~\$40
Income Tax Expense	\$0 – \$10
GAAP Net Loss	(\$85) – (\$125)
GAAP Net Loss per Share	(\$0.53) – (\$0.78)
Non-GAAP Net Income	\$60 – \$100
Non-GAAP Diluted EPS	\$0.37 – \$0.62
Capital Expenditures	~\$40

*R&D expense expectations for 2021 include a potential \$25 million milestone payment to the former shareholders of Rodin related to the anticipated submission of an investigational new drug application, or equivalent, for ALKS 1140, the first clinical candidate to emerge from the histone deacetylase (HDAC) inhibitor platform acquired by the company in late 2019.

Recent Events:

LYBALVI (formerly referred to as ALKS 3831)

- In December 2020, the FDA acknowledged receipt of the company's New Drug Application (NDA) resubmission for LYBALVI and assigned the application a new Prescription Drug User Fee Act (PDUFA) target action date of June 1, 2021. Subsequent to Alkermes' resubmission of the NDA, the FDA issued a new request for records under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to supplement the information previously provided by the company. The resubmission and records request followed the company's receipt of a Complete Response Letter (CRL) from the FDA in November 2020 following its remote review of records relating to the manufacture of LYBALVI at the company's Wilmington, OH facility. The CRL did not identify or raise any concerns about the clinical or non-clinical data in the NDA and the FDA has not asked the company to complete any new clinical trials to support approval of the application.

Nemvaleukin alfa ("nemvaleukin", formerly referred to as ALKS 4230)

- In November 2020, preliminary data from ARTISTRY-1 and ARTISTRY-2, phase 1/2 studies evaluating nemvaleukin administered intravenously and subcutaneously, respectively, as monotherapy and in combination with pembrolizumab in patients with refractory advanced solid

tumors, were presented at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting.

HDAC-inhibitor platform

- In December 2020, the company nominated ALKS 1140, a novel CoREST²-selective HDAC inhibitor candidate with potential applications in neuropsychiatric indications. First-in-human studies for ALKS 1140 are planned to begin in 2021.

Other

- In January 2021, results from a National Institute on Drug Abuse (NIDA)-funded study evaluating the efficacy and safety of naltrexone for extended-release injectable suspension (XR-NTX) administered once every three weeks plus oral extended-release bupropion administered daily as a combination treatment for adults with moderate or severe methamphetamine use disorder (MUD) were published by Dr. Madhukar H. Trivedi et al. in the New England Journal of Medicine (NEJM).³

Corporate

- In December 2020, the company announced a Value Enhancement Plan designed to drive growth, improve operational and financial performance and enhance shareholder value. The plan includes a commitment to multi-year profitability targets, a review and optimization of the company's cost structure and potential monetization of non-core assets.
- In December 2020, two new, independent directors joined the company's board of directors (Board). David Daglio brings to the Board more than 20 years of experience in institutional investment management, and Brian McKeon brings strong financial and management expertise as well as public company executive and director experience.
- In January 2021, Blair C. Jackson was appointed Chief Operating Officer and Iain M. Brown was named Chief Financial Officer. They will oversee the company's implementation of the Value Enhancement Plan.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (1:00 p.m. GMT) on Thursday, Feb. 11, 2021, 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. GMT) on Thursday, Feb. 11, 2021, through Thursday, Feb. 18, 2021, 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 13715619.

About Alkermes plc

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

Non-GAAP Financial Measures

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

Non-GAAP net income (loss) adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; 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 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 our 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 expected drivers of future value creation, expectations of revenue growth and diversification of the company's commercial portfolio and the anticipated improvement in patient access to healthcare providers and to the company's commercial products; the company's ability to execute on its strategic priorities and plans to manage for long-term profitability through execution of its Value Enhancement Plan, including through the achievement of multi-year profitability targets, review and optimization of its cost structure and potential monetization of non-core assets; the potential therapeutic and commercial value of the company's marketed and development products; the FDA's target PDUFA action date for, and potential approval of, the NDA for LYBALVI; expectations concerning future development activities, including advancement of the nemvaleukin development program and the anticipated submission of an IND or equivalent for ALKS 1140 and plans to initiate related studies; and expectations concerning the company's commercial activities, including investments to support the anticipated launch of LYBALVI. 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 company's cost structure review and optimization may not yield the intended results; the company may not be able to achieve its targeted profitability metrics in a timely manner or at all; 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 healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia and on patient and healthcare provider access to the company's commercial products and impacts on the regulatory agencies with which the company interacts in the development, review, approval and commercialization of its medicines; 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 the adequacy of the data and other information included in our submissions to support the FDA's requirements for approval; clinical development activities may not be completed on time or at all; the results of the company's development activities may not be positive, or predictive of real-world results or of results in subsequent trials, and preliminary or interim results of the company's development activities may not be predictive of final results of such activities, results of future preclinical or clinical trials or real-world results; 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 LYBALVI; 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, 2020 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

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

(tables follow)

¹ The term "ARISTADA" as used in this press release refers to ARISTADA and ARISTADA INITIO®, unless the context indicates otherwise.

² CoREST: Co-repressor of repressor element-1 silencing transcription factor.

³ Trivedi MH, Walker R, Ling W, et al. Bupropion and Naltrexone in Methamphetamine Use Disorder. *New England Journal of Medicine*, 2021;384:140-53. DOI: 10.1056/NEJMoa2020214.

Alkermes plc and Subsidiaries Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended December 31, 2020	Three Months Ended December 31, 2019
Revenues:		
Product sales, net	\$ 148,961	\$ 149,609
Manufacturing and royalty revenues	130,893	107,287
Research and development revenue	141	11,084
License revenue	—	144,750
Total Revenues	<u>279,995</u>	<u>412,730</u>
Expenses:		
Cost of goods manufactured and sold	42,922	46,482
Research and development	112,107	198,157
Selling, general and administrative	145,778	154,453
Amortization of acquired intangible assets	9,917	10,171
Restructuring expense	—	13,401
Total Expenses	<u>310,724</u>	<u>422,664</u>
Operating Loss	<u>(30,729)</u>	<u>(9,934)</u>
Other (Expense) Income, net:		
Interest income	1,036	3,191
Interest expense	(1,869)	(3,196)
Change in the fair value of contingent consideration	(12,681)	5,000
Other income, net	2,597	2,382
Total Other (Expense) Income, net	<u>(10,917)</u>	<u>7,377</u>
Loss Before Income Taxes	<u>(41,646)</u>	<u>(2,557)</u>
Provision for Income Taxes	996	2,797
Net Loss — GAAP	<u>\$ (42,642)</u>	<u>\$ (5,354)</u>
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.03)</u>
Non-GAAP earnings per share — basic and diluted	<u>\$ 0.10</u>	<u>\$ 0.83</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	<u>159,153</u>	<u>157,662</u>
Basic — Non-GAAP	<u>159,153</u>	<u>157,662</u>
Diluted — Non-GAAP	<u>161,267</u>	<u>159,073</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
Net Loss — GAAP	\$ (42,642)	\$ (5,354)
Adjustments:		
Share-based compensation expense	24,884	21,387
Depreciation expense	10,411	10,340
Amortization expense	9,917	10,171
Income tax effect related to reconciling items	1,121	592
Non-cash net interest expense	166	168
Change in the fair value of contingent consideration	12,681	(5,000)
Change in the fair value of warrants	—	(930)
Acquisition of IPR&D	—	86,595
Restructuring expense	—	13,401
Non-GAAP Net Income	<u>\$ 16,538</u>	<u>\$ 131,370</u>

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Year Ended December 31, 2020	Year Ended December 31, 2019
Revenues:		
Product sales, net	\$ 551,760	\$ 524,499
Manufacturing and royalty revenues	484,000	447,882
Research and development revenue	1,946	52,816
License revenue	1,050	145,750
Total Revenues	<u>1,038,756</u>	<u>1,170,947</u>
Expenses:		
Cost of goods manufactured and sold	178,316	180,385
Research and development	394,588	512,833
Selling, general and administrative	538,827	599,449
Amortization of acquired intangible assets	39,452	40,358
Restructuring expense	—	13,401
Total Expenses	<u>1,151,183</u>	<u>1,346,426</u>
Operating Loss	<u>(112,427)</u>	<u>(175,479)</u>
Other Income (Expense), net:		
Interest income	6,960	13,976
Interest expense	(8,659)	(13,601)
Change in the fair value of contingent consideration	3,945	(22,800)
Other income, net	13,644	848
Total Other Income (Expense), net	<u>15,890</u>	<u>(21,577)</u>
Loss Before Income Taxes	<u>(96,537)</u>	<u>(197,056)</u>
Provision (Benefit) for Income Taxes	14,324	(436)
Net Loss — GAAP	<u>\$ (110,861)</u>	<u>\$ (196,620)</u>
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	<u>\$ (0.70)</u>	<u>\$ (1.25)</u>
Non-GAAP earnings per share — basic and diluted	<u>\$ 0.43</u>	<u>\$ 0.71</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	<u>158,803</u>	<u>157,051</u>
Basic — Non-GAAP	<u>158,803</u>	<u>157,051</u>
Diluted — Non-GAAP	<u>159,861</u>	<u>159,056</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
Net Loss — GAAP	\$ (110,861)	\$ (196,620)
Adjustments:		
Share-based compensation expense	90,161	100,977
Depreciation expense	42,402	40,055
Amortization expense	39,452	40,358
Income tax effect related to reconciling items	10,092	5,762
Non-cash net interest expense	666	673
Change in the fair value of contingent consideration	(3,945)	22,800
Change in the fair value of warrants	—	(1,837)
Acquisition of IPR&D	674	86,595
Restructuring expense	—	13,401
Non-GAAP Net Income	<u>\$ 68,641</u>	<u>\$ 112,164</u>

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	December 31, 2020	December 31, 2019
Cash, cash equivalents and total investments	\$ 659,807	\$ 614,370
Receivables	275,143	257,086
Contract assets	14,401	8,386
Inventory	125,738	101,803
Prepaid expenses and other current assets	60,662	59,716
Property, plant and equipment, net	350,003	362,168
Intangible assets, net and goodwill	204,064	243,516
Other assets	259,912	158,358
Total Assets	\$ 1,949,730	\$ 1,805,403
Long-term debt — current portion	\$ 2,843	\$ 2,843
Other current liabilities	435,415	388,269
Long-term debt	272,118	274,295
Contract liabilities — long-term	16,397	22,068
Other long-term liabilities	155,975	32,486
Total shareholders' equity	1,066,982	1,085,442
Total Liabilities and Shareholders' Equity	\$ 1,949,730	\$ 1,805,403
Ordinary shares outstanding (in thousands)	159,161	157,779

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Annual Report on Form 10-K for the year ended December 31, 2020, which the company intends to file in February 2021.

Alkermes plc and Subsidiaries
Revenues for Calendar Year 2020 and 2019

(In thousands)	Three Months Ended March 31, 2020	Three Months Ended June 30, 2020	Three Months Ended September 30, 2020	Three Months Ended December 31, 2020	Year Ended December 31, 2020
Revenues:					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	\$ 82,243	\$ 83,114	\$ 87,876	\$ 92,327	\$ 345,560
VIVITROL	78,769	71,646	80,258	80,049	310,722
ARISTADA	50,957	58,769	62,400	68,912	241,038
Key Commercial Product Revenues	211,969	213,529	230,534	241,288	897,320
Legacy Product Revenues	34,008	33,391	32,475	38,566	138,440
License Revenue	—	—	1,050	—	1,050
Research and Development Revenues	243	609	953	141	1,946
Total Revenues	\$ 246,220	\$ 247,529	\$ 265,012	\$ 279,995	\$ 1,038,756

(In thousands)	Three Months Ended March 31, 2019	Three Months Ended June 30, 2019	Three Months Ended September 30, 2019	Three Months Ended December 31, 2019	Year Ended December 31, 2019
Revenues:					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	\$ 75,605	\$ 91,863	\$ 76,716	\$ 79,147	\$ 323,331
VIVITROL	69,183	88,199	85,164	92,818	335,364
ARISTADA	30,298	48,436	53,610	56,791	189,135
Key Commercial Product Revenues	175,086	228,498	215,490	228,756	847,830
Legacy Product Revenues	33,310	36,034	27,067	28,140	124,551
License Revenue (2)	—	1,000	—	144,750	145,750
Research and Development Revenues	14,706	14,340	12,686	11,084	52,816
Total Revenues	\$ 223,102	\$ 279,872	\$ 255,243	\$ 412,730	\$ 1,170,947

(1) - Includes RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA.

(2) - Includes a milestone payment received in the fourth quarter of 2019 which was allocated to the license sold to Biogen in connection with the VUMERITY collaboration.

Alkermes plc and Subsidiaries
2021 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)	160	\$ (0.66)
Adjustments:			
Share-based compensation expense	93.0		
Depreciation expense	46.0		
Amortization expense	40.0		
Income tax effect related to reconciling items	5.0		
Non-cash net interest expense	1.0		
Projected Net Income — Non-GAAP	<u>\$ 80.0</u>	161	\$ 0.50

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



Fourth Quarter and Year-End 2020 Financial Results & Business Update

February 11, 2021



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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 potential growth of revenue from its commercial products, potential diversification of its product portfolio, therapeutic areas that the company may pursue and the company's plans to manage for growth and long-term profitability through execution of its Value Enhancement Plan, including its commitment to profitability targets, optimization of its cost structure and exploration of strategic opportunities; 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 timelines, plans and expectations for development activities relating to the company's products and product development candidates in both neuroscience and oncology, including (i) for nemvaleukin alfa ("nemvaleukin"), plans to initiate additional studies with IV nemvaleukin, select additional tumor types to pursue, and explore strategic collaborations and (ii) for ALKS 1140, plans to begin phase 1 first-in-human trials; and 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 LYBALVI™ and plans to advance discussions on registration plans for nemvaleukin with regulatory agencies. 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. These risks, assumptions 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; 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 NDAs, including clinical trial designs, conduct and methodologies, manufacturing processes and facilities, or the adequacy of the data or other information included in the company's regulatory submissions to support the FDA's requirements for approval; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products, including with respect to the NDA for LYBALVI; the company's development activities may not be completed on time or at all; the results of the company's development activities may not be positive, or predictive of real-world results or of results in subsequent trials, and preliminary or interim results of the company's development activities may not be predictive of final results of such activities, results of future preclinical or clinical trials or real-world results; the company and its licensees may not be able 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, assumptions and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 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, 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 Feb. 11, 2021.

Note Regarding Trademarks: The company is the owner of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA®, ARISTADA INITIO®, LYBALVI™ and VIVITROL®. VUMERITY® is a registered trademark of Biogen MA Inc., used by Alkermes under license. 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.



Agenda

- **Introduction**
Sandy Coombs, VP, Investor Relations
- **Corporate Update**
Richard Pops, Chief Executive Officer
- **Q4 & FY 2020 Financial Results; 2021 Financial Expectations**
Iain Brown, Chief Financial Officer
- **Q4 & FY 2020 Commercial Review**
Todd Nichols, Chief Commercial Officer
- **R&D Pipeline Update**
Richard Pops, Chief Executive Officer



Execution Against Our Strategic Priorities

2020 Key Accomplishments

Commercial Execution

- VIVITROL® and ARISTADA®
 - Strong performance in a complex environment
 - Adapted commercial strategy in response to COVID-19
- Prepared for synergistic launch of LYBALVI™ (ALKS 3831) within psychiatry portfolio
- Supported launch of VUMERITY®

Advancement of Highest Potential R&D Programs

- Completed successful Advisory Committee meeting for LYBALVI*
- Advanced nemvaleukin alfa (ALKS 4230) development program
 - Observed anti-tumor activity in monotherapy and combination settings with intravenous administration
 - Accelerated patient enrollment and expanded clinical trial network globally
- Nominated first clinical candidate from HDAC** inhibitor program

Efficient Management of Operating Structure and Strong Governance

- Adapted cost structure in response to COVID-19-related disruptions
- Announced Value Enhancement Plan
 - Commitment to profitability targets
 - Focus on strategic opportunities
- Continued Board refreshment
 - Appointed two new independent directors
 - Announced upcoming retirement of two long-serving directors

*NDA resubmission under review following FDA Complete Response Letter and records requests relating to manufacturing of LYBALVI. **HDAC: histone deacetylase

Focus on Value Creation in 2021: Three Key Components

1

Grow and Diversify Commercial Revenues

- Drive VIVITROL® and ARISTADA® net sales
- Support VUMERITY® growth
- Launch LYBALVI™ (PDUFA* June 1, 2021)

2

Demonstrate Value of R&D Investments

- Nemvaleukin alfa
 - Determine registration pathway
 - Demonstrate anti-tumor activity
 - Explore strategic collaboration
- ALKS 1140 (CoREST** selective HDAC inhibitor)
 - Initiate phase 1/FIH study
- Investor Day
 - Provide update on pipeline platforms and programs

3

Manage for Growth & Long-Term Profitability

- Operationalize commitment to profitability targets
- Optimize cost structure and drive operating leverage
- Explore strategic opportunities to maximize value and enhance profitability

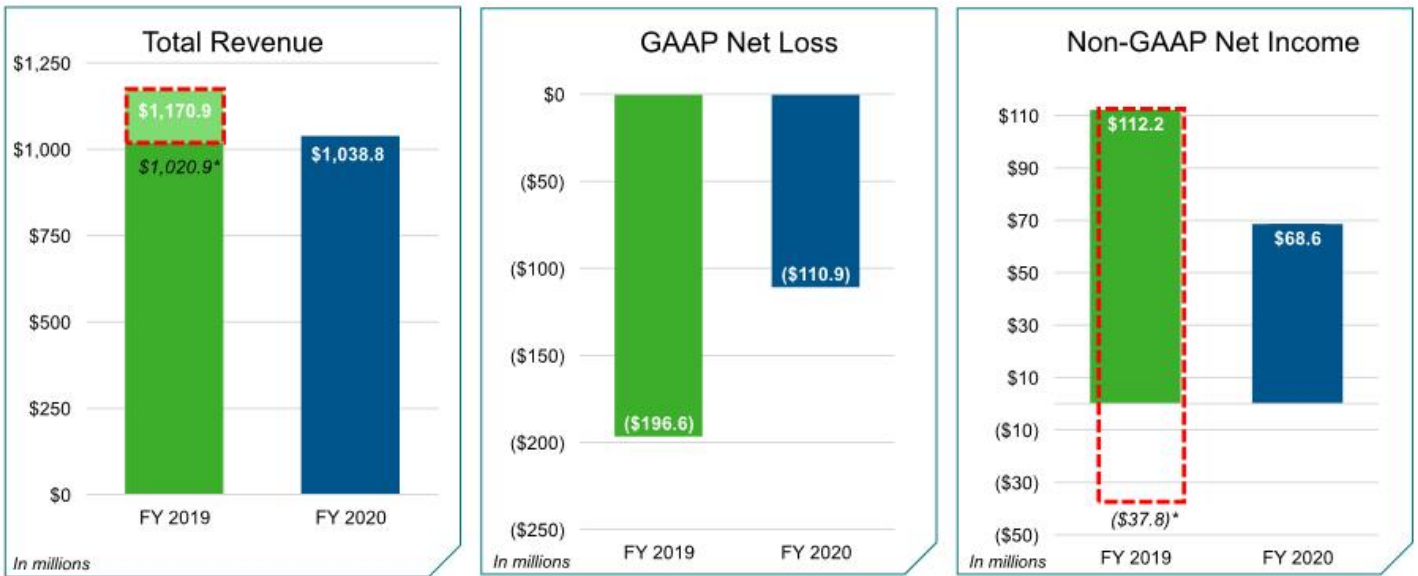
*Prescription Drug User Fee Act

**Co-repressor of repressor element-1 silencing transcription factor

Alkermes

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Full-Year 2020 Financial Results Summary



Represents \$150.0 million milestone payment from Biogen related to FDA approval of VUMERITY® in Q4 2019.

*Amount excludes \$150.0 million milestone payment from Biogen.

Fourth Quarter 2020 Revenue Summary

<i>In millions, except %</i>	Q4'20	Q4'19	Δ Q4'20 vs. Q4'19
VIVITROL®	\$80.0*	\$92.8	(14%)*
ARISTADA®	\$68.9	\$56.8	21%
Manufacturing & Royalty Revenue	\$130.9	\$107.3	22%
R&D Revenue	\$0.1	\$11.1 [†]	NA
License Revenue	-	\$144.8 [‡]	NA
Total Revenue	\$280.0	\$412.7	(32%)

*Decrease in VIVITROL net sales in Q4 '20 was primarily due to COVID-19 pandemic-related disruptions.

[†]Includes \$5.2M of the \$150M milestone payment from Biogen related to FDA approval of VUMERITY® recorded as R&D revenue.

[‡]Includes \$144.8M of the \$150M milestone payment from Biogen related to FDA approval of VUMERITY recorded as license revenue.

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

2020 Revenue Summary

<i>In millions, except %</i>	FY 2020	FY 2019	Δ 2020 vs. 2019
VIVITROL®	\$310.7*	\$335.4	(7%)*
ARISTADA®	\$241.0	\$189.1	27%
Manufacturing & Royalty Revenue	\$484.0	\$447.9	8%
R&D Revenue	\$1.9	\$52.8†	NA
License Revenue	\$1.1	\$145.8‡	NA
Total Revenue	\$1,038.8	\$1,170.9	(11%)

*Decrease in VIVITROL net sales in FY 2020 was primarily due to COVID-19 pandemic-related disruptions.

†Includes \$5.2M of the \$150M milestone payment from Biogen related to FDA approval of VUMERITY® recorded as R&D revenue.

‡Includes \$144.8M of the \$150M milestone payment from Biogen related to FDA approval of VUMERITY recorded as license revenue.

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

Alkermes: 2021 Financial Expectations†*

<i>(in millions, except per share amounts)</i>	Financial Expectations for Year Ending Dec. 31, 2021	
Revenues	\$1,100 – \$1,170	<p>Expected net sales of proprietary products:</p> <ul style="list-style-type: none"> • VIVITROL® net sales of \$315M – \$345M • ARISTADA® net sales of \$260M – \$290M • LYBALVI™ net sales of <\$10M* <p>Operating expenses:</p> <ul style="list-style-type: none"> • R&D expense includes \$25M potential milestone payment related to ALKS 1140
COGS	\$190 – \$200	
R&D Expense	\$400 – \$430	
SG&A Expense	\$570 – \$600	
Amortization of Intangible Assets	~\$40	
Income Tax Expense	\$0 – \$10	
GAAP Net Loss	(\$85) – (\$125)	
GAAP Net Loss Per Share	(\$0.53) – (\$0.78)	
Non-GAAP Net Income‡	\$60 – \$100	
Non-GAAP Earnings Per Share (Diluted)	\$0.37 – \$0.62	

† These expectations are provided by Alkermes plc (the "Company") in its Current Report on Form 8-K filed with the SEC on Feb. 11, 2021 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

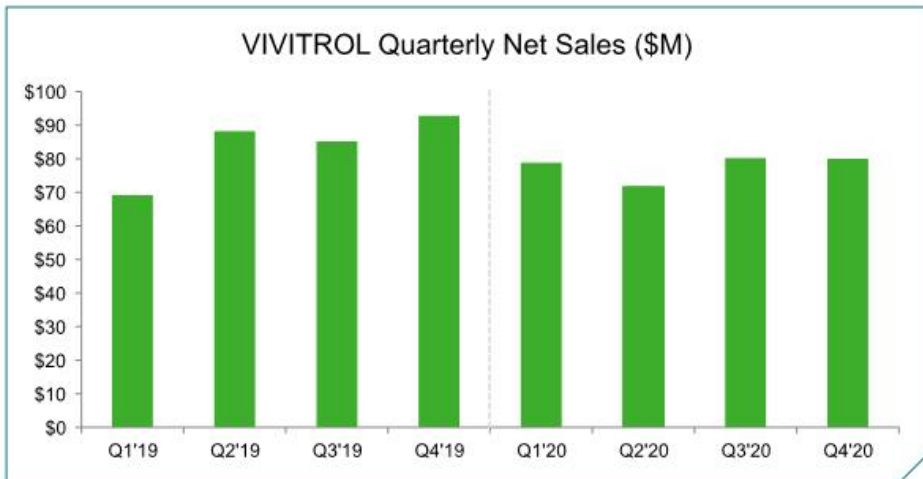
* Ranges provided are based on recent trends and assume continuation of such trends into the first half of the year, and an anticipated improvement in patient access to treatment providers and to the Company's commercial products in the second half of the year. If patient access does not improve as anticipated, or if new COVID-19-related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.

‡ 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 contingent consideration; 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 Feb. 11, 2021.

* Pending approval. PDUFA target action date is June 1, 2021.



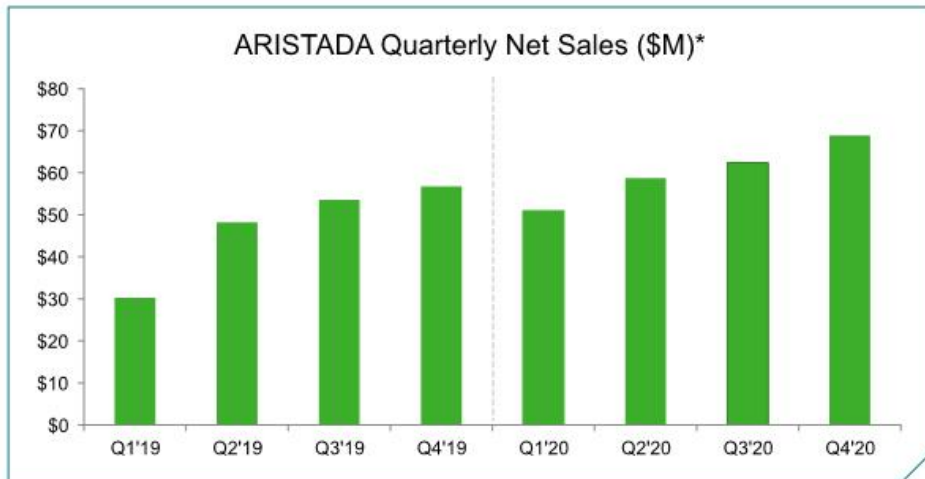
VIVITROL® Performance and Expectations



* These expectations are provided by the Company in its Current Report on Form 8-K filed with the SEC on Feb. 11, 2021 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations. These expectations are provided based on recent trends and assume continuation of such trends into the first half of the year and an anticipated improvement in patient access to treatment providers and to the Company's commercial products in the second half of the year. If patient access does not improve as anticipated, or if new COVID-19-related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.

- FY'20 year-over-year net sales decline of **7%** to \$310.7M, driven by unit decline of **8%**
 - Gross-to-net deductions: 50% in FY'20, compared to 48% in FY'19
 - Minimal inventory build of approximately \$1.5M in Q4'20
- FY'21 net sales expected to range from **\$315M - \$345M***
 - Expected gross-to-net deductions: 54%
 - Q1'21 net sales expected to be \$65M - \$70M

ARISTADA® Performance and Expectations

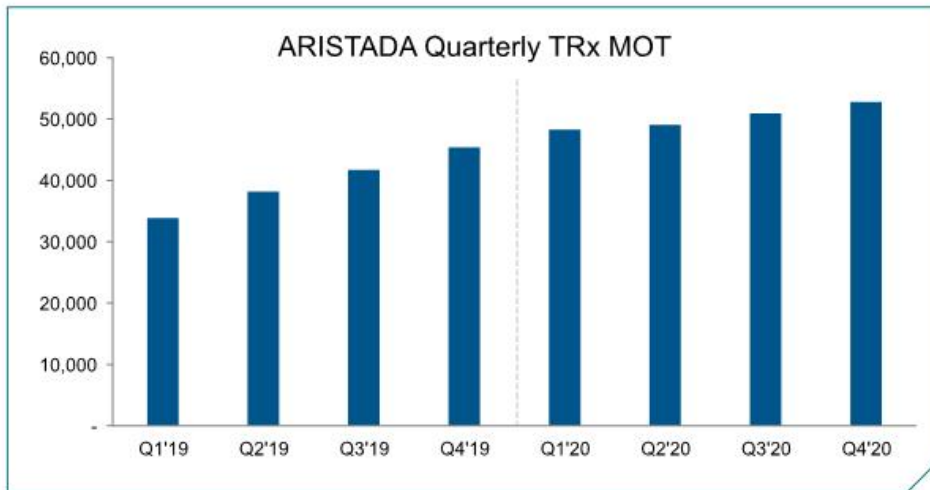


*Inclusive of ARISTADA INITIO®

† These expectations are provided by the Company in its Current Report on Form 8-K filed with the SEC on Feb. 11, 2021 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations. These expectations are provided based on recent trends and assume continuation of such trends into the first half of the year and an anticipated improvement in patient access to treatment providers and to the Company's commercial products in the second half of the year. If patient access does not improve as anticipated, or if new COVID-19-related disruptions emerge, the Company's ability to meet these expectations could be negatively impacted.

- FY'20 year-over-year net sales growth of **27%** to \$241.0M, driven by unit growth of **30%**
 - Gross-to-net deductions: 53% in FY'20, compared to 49% in FY'19
 - Inventory levels increased by approximately \$5.2M in Q4'20
- FY'21 net sales expected to range from **\$260M - \$290M** †
 - Expected gross-to-net deductions: 55%
 - Q1'21 net sales expected to be \$50M - \$55M

ARISTADA®: Prescription Growth Trends



Source: IQVIA NPA

- Q4 year-over-year **growth of 16%** on TRx months of therapy (MOT) basis
 - Outpaced overall atypical long-acting injectable (LAI) market Q4 year-over-year growth of 5%
- Market share:
 - TRx MOT: **9.1%** of atypical LAI market prescriptions in Q4 '20

Advancing Neuroscience Development Programs

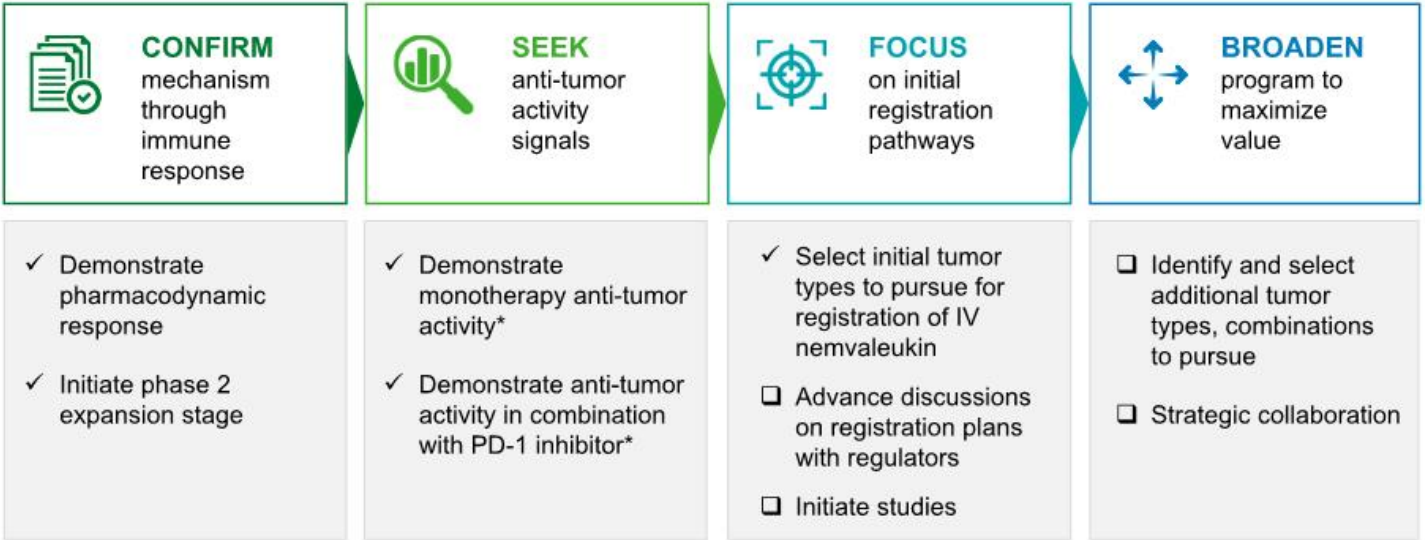


- Daily oral investigational antipsychotic designed to offer efficacy of olanzapine; addition of samidorphan intended to mitigate olanzapine-associated weight gain
- NDA resubmission and response to records request under review by FDA; PDUFA date June 1, 2021

ALKS 1140

- Novel investigational CoREST-selective HDAC inhibitor
- First-in-human trials expected to begin in 2021
 - Initial clinical development plans focused on basket of indications, including rare neurodegenerative and neurodevelopmental diseases as well as common psychiatric diseases

Nemvaleukin Development Strategy



*Anti-tumor activity observed in ARTISTRY-1 evaluating nemvaleukin administered intravenously.

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