Eagle Pharmaceuticals Reports First Quarter 2022 Results

May 9, 2022

- Q1 2022 net income was $3.47 per basic and $3.41 per diluted share and adjusted non-GAAP net income* was $4.10 per basic and $4.04 per diluted share
- Q1 2022 total revenue was $115.9 million, up from $41.2 million in Q1 2021
- Achieved sales of $34.3 million of vasopressin, with prior four weeks average market share of 24% per IQVIA data
- Achieved sales of $37.2 million of PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®
- Agreed to terms to acquire Acacia Pharma Group plc, including two FDA-approved, NCE hospital-based products; expected to close in June 2022, subject to satisfaction of closing conditions
- Remains on track to support submission of new drug application later this month for landiolol, a beta-1 adrenergic blocker
- Expects to start clinical trial in CAL02 patients in Q3 2022 during pneumonia season
- Key objective to pursue additional potential transactions near-term to further diversify product portfolio and pipeline

WOODCLIFF LAKE, N.J., May 09, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three months ended March 31, 2022.

Business and Recent Highlights:

- Achieved first quarter 2022 sales of $34.3 million for vasopressin, an A-rated generic alternative to Vasostrict®, which the Company began shipping on January 18, 2022, with 180 days of marketing exclusivity. U.S. sales of Vasostrict totaled $901.7 million for the 12 months ended December 31, 2021, as reported by Endo International plc.
- Achieved first quarter 2022 sales of $37.2 million of PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. PEMFEXY is a ready-to-use liquid with a unique J-code and is approved in the U.S. to treat nonsquamous non-small cell lung cancer and mesothelioma. The ALIMTA U.S. market totaled $1.2 billion for the 12 months ended December 31, 2021, as reported by Eli Lilly and Company.
- As previously announced, reached agreement on the proposed terms of a transfer of the entire issued and to be issued share capital of Acacia Pharma Group plc ("Acacia") to Eagle. The transaction is expected to close in June 2022, subject to satisfaction of closing conditions. The proposed transaction is expected to provide Eagle with two currently marketed, acute care, hospital products, both of which are new chemical entities ("NCEs") with strong patent protection:
  - BARHEMSYS, the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting, and
  - BYFAVO[1] indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.
- Remains on track to support NDA filing by AOP Health Group ("AOP Health"), with whom Eagle entered into a licensing agreement in August 2021, for landiolol, a beta-1 adrenergic blocker, later this month.
- Expects to start phase 2b/3 clinical trial in CAL02 patients in Q3 2022 during pneumonia season.
- Reached a settlement agreement with Hospira, Inc., related to BENDEKA® (bendamustine hydrochloride). Eagle had asserted two Orange Book-listed patents against Hospira related to its NDA referencing BENDEKA. The settlement agreement provides that Hospira has the right to market its product beginning January 17, 2028, or earlier based on certain circumstances.

- Anticipates strong growth for 2022; key objective to pursue additional potential transactions to continue diversifying its commercial product portfolio and pipeline.

Financial Highlights

First Quarter 2022

- Total revenue for Q1 2022 was $115.9 million, compared to $41.2 million in Q1 2021, primarily reflecting strong product sales of vasopressin and PEMFEXY.
- Q1 2022 net income was $44.1 million, or $3.47 per basic and $3.41 per diluted share, compared to net loss of $0.4 million, or $0.03 per basic and diluted share, in Q1 2021.
- Q1 2022 adjusted non-GAAP net income* was $52.2 million, or $4.10 per basic and $4.04 per diluted share, compared to adjusted non-GAAP net income of $3.2 million, or $0.24 per basic and diluted share, in Q1 2021.
- Cash and cash equivalents were $69.5 million, net accounts receivable was $130.9 million, and debt was $24.0 million as of March 31, 2022. The Company had considerable cash outlays for the launch of vasopressin and PEMFEXY and repurchased $8.1 million of the Company stock in Q1 2022.

“The early momentum we saw at the beginning of 2022 has continued to build. We posted a great first quarter, reflecting the strong initial sales of vasopressin and PEMFEXY. We continue to strengthen our cash position, expect to acquire a company with two commercial assets, and significantly diversify our product portfolio,” stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. “Looking ahead, we plan to put our cash and balance sheet to good use as we seek to further broaden our product offerings and pipeline and to expand our presence in the acute care and oncology spaces through potential acquisitions or licensing deals,” concluded Tarriff.

First Quarter 2022 Financial Results

Total revenue for the three months ended March 31, 2022, was $115.9 million, as compared to $41.2 million for the three months ended March 31, 2021. A summary of total revenue by product is outlined below:

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	(unaudited)
Revenue (in thousands):		
PEMFEXY™	$ 37,182	$ —
vasopressin	34,345	—
RYANODEX®	6,605	6,782
BELRAPZO®	5,949	5,693
BENDEKA®	4,553	3,615
TREAKISYM	1,454	1,030
Product sales, net	90,088	17,120
BENDEKA®	23,823	23,808
TREAKISYM	1,963	321
Royalty revenue	25,786	24,129
Total revenue	**$ 115,874**	**$ 41,249**

Gross margin was 76% during the first quarter of 2022, as compared to 74% in the first quarter of 2021. The increase in gross margin for the first quarter of 2022 was driven by the benefit of launch costs recognized in prior periods.

R&D expense was $6.1 million for the first quarter of 2022, compared to $14.3 million for the first quarter of 2021. The decrease was primarily due to the non-recurrence of development cost on vasopressin and lower spend on fulvestrant and RYANODEX related projects. Excluding stock-based compensation and other non-cash and non-recurring items, adjusted non-GAAP R&D expense* during the first quarter of 2022 was $5.4 million.

SG&A expenses in the first quarter of 2022 totaled $22.2 million compared to $19.9 million in the first quarter of 2021. This increase was primarily related to external legal spend for the anticipated acquisition of Acacia and sales and marketing costs for the launch of PEMFEXY partially offset by a decrease in stock-based compensation expense. Excluding stock-based compensation and other non-cash and non-recurring items, first quarter 2022 adjusted non-GAAP SG&A expense* was $16.6 million.

Net income for the first quarter of 2022 was $44.1 million, or $3.47 per basic and $3.41 per diluted share, compared to net loss of $0.4 million, or $0.03 per basic and diluted share, in the first quarter of 2021, as a result of the factors discussed above.

Adjusted non-GAAP net income* for the first quarter of 2022 was $52.2 million, or $4.10 per basic and $4.04 per diluted share, compared to adjusted non-GAAP net income* of $3.2 million, or $0.24 per basic and diluted share, in the first quarter of 2021.

2022 Full Year Expense Guidance

- Adjusted non-GAAP R&D expense* is expected to be in the range of $46 million to $50 million, as compared to $32.5 million in 2021.

- Adjusted non-GAAP SG&A expense* is expected to be in the range of $54 million to $58 million, as compared to $54.9 million in 2021.

- The guidance excludes expense for operating Acacia in the event of successful acquisition.

Liquidity

As of March 31, 2022, Eagle had $69.5 million in cash and cash equivalents plus $130.9 million in net accounts receivable, and $24.0 million in outstanding debt. Therefore, as of March 31, 2022, Eagle had net cash plus receivables of $176.4 million.

In the first quarter of 2022, Eagle repurchased $8.1 million of its common stock as part of its current $160.0 million Share Repurchase Program. From August 2016 through March 31, 2022, Eagle has repurchased $236.1 million of its common stock.

Conference Call

As previously announced, Eagle management will host its first quarter 2022 conference call as follows:

Date	Monday, May 9, 2022
Time	8:30 A.M. ET
Toll free (U.S.)	800-891-3840
International	203-518-9544
Webcast (live and replay)	www.eagleus.com, under the “Investor + News” section

A replay of the conference call will be available for one week after the call's completion by dialing 888-562-2826 (US) or 402-220-7355 (International) and entering conference call ID EGRXQ122. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients’ lives. Eagle’s commercialized products include vasopressin, PEMFEXY™, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM (Japan), and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle’s website at www.eagleus.com.

Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the Company’s financial projections and guidance, including anticipated financial performance for 2022, including expected R&D and SG&A expense; the expected structure, anticipated synergies, terms, timing and closing of the proposed transaction with Acacia Pharma; statements regarding the commercial potential for BARHEMSYS and BYFAVO and other products or product candidates; the Company’s ability to pursue additional potential transactions to further diversify its product portfolio and pipeline on favorable terms or at all; the Company’s ability to obtain and maintain regulatory approval of its products and product candidates; the Company's clinical development plan for its product candidates, including the number and timing of development initiatives or new indications for the Company’s product candidates; the Company’s timing and ability to enroll patients in upcoming clinical trials, including for CAL02; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates, including landiolol and its fulvestrant product; the progress and success of the Company’s launch of any products, including vasopressin and PEMFEXY; the addressable market size for, and the ability of the Company to successfully commercialize, its product candidates, including vasopressin and PEMFEXY; the ability of vasopressin to benefit providers and patients as an alternative to Vasostrict; the period of marketing exclusivity for any of the Company’s products or product candidates, including vasopressin; the resolution of patent litigation and all related settlement terms, including the date of market entry and the potential for earlier market entry under certain circumstances; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates and the Company’s ability to maintain regulatory approval of its products and product candidates; the Company's clinical development plan for the product candidates in its portfolio; the implementation of certain healthcare reform measures; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the success of the Company's collaborations with its strategic partners and the timing and results of these partners’ preclinical studies and clinical trials, and the Company’s potential earnings potential through such collaborations; the ability of the Company’s executive team to execute on the Company’s strategy and to utilize its cash and other assets to increase shareholder value; and the ability of the Company’s product candidates to deliver value to stockholders; the Company's ability to deliver value in 2022 and over the long term; the Company’s ability to utilize its cash and other assets to increase shareholder value; the Company’s ability to effectively manage and control expenses in line with its budget; and the Company's plans and ability to advance the products in its pipeline; potential opportunities for, and the Company’s ability to complete, business development transactions, in a timely manner, on favorable terms to the Company, or at all; the sufficiency of the Company’s cash flows and capital resources; and the Company’s ability to achieve expected future financial performance and results. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the risk that the transaction with Acacia Pharma is not consummated or that the benefits of the transaction are not realized; the impacts of the COVID-19 pandemic and geopolitical events such as the ongoing military conflict between Ukraine and Russia and related sanctions against Russia, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in

regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy, and the overall impact of the COVID-19 pandemic on the Company's business, financial condition and results of operations; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of our products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic and geopolitical events, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; factors in addition to the foregoing that may impact the Company's financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause the Company's actual results and outcomes to materially differ from its projections and guidance; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022 and its other subsequent filings with the SEC, including the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which the Company expects to file with the SEC on May 9, 2022. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share attributable to Eagle, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense. The Company believes these measures provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Adjusted non-GAAP net income and related earnings per share information excludes amortization expense, stock-based compensation expense, depreciation expense, severance, acquisition related costs, legal settlement, non-cash interest expense, fair value adjustments on equity investment, convertible promissory note related credit losses, fair value adjustments related to derivative instruments, accretion of discount on convertible promissory note and the tax effect of these adjustments.

Adjusted non-GAAP R&D expense excludes stock-based compensation expense and depreciation expense.

Adjusted non-GAAP SG&A expense excludes stock-based compensation expense, amortization expense, depreciation expense, severance, legal settlement and acquisition related costs.

The Company believes the use of non-GAAP financial measures helps indicate underlying trends in the Company's business and are important in comparing current results with prior period results and understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ongoing results. See the attached reconciliation tables for details of the amounts excluded and included to arrive at certain of the non-GAAP financial measures.

Investors should note that reconciliations of the forward-looking or projected non-GAAP financial measures included in this press release to their most comparable GAAP financial measures cannot be provided because the Company cannot do so without unreasonable efforts due to the unavailability of information needed to calculate the reconciling items and the variability, complexity, and limited visibility of comparable GAAP measures, and the reconciling items that would be excluded from the non-GAAP financial measures in the future. Reconciliations of the components of projected adjusted non-GAAP R&D and adjusted non-GAAP SG&A to their most comparable GAAP financial measures is not provided because the quantification of projected GAAP R&D and SG&A and the reconciling items between projected GAAP to adjusted non-GAAP R&D and SG&A cannot be reasonably calculated or predicted at this time without unreasonable efforts. For example, with respect to GAAP R&D and SG&A, the Company is not able to calculate the favorable or unfavorable expenses related to the fair value adjustments on equity investments and derivative instruments primarily due to nature of these transactions. Such unavailable information could be significant such that actual GAAP R&D and SG&A would vary significantly from projected GAAP and adjusted non-GAAP R&D and adjusted non-GAAP SG&A.

These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. The Company strongly encourages investors to review its consolidated financial statements and publicly-filed reports in their entirety and cautions investors that the non-GAAP financial measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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-- Financial tables follow –

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share amounts)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,522	$ 97,659
Accounts receivable, net	130,858	41,149
Inventories	24,818	21,908
Prepaid expenses and other current assets	14,968	11,890
Total current assets	240,166	172,606
Property and equipment, net	1,627	1,636
Intangible assets, net	9,940	10,671
Goodwill	39,743	39,743
Deferred tax asset, net	21,231	18,798
Other assets	7,458	10,278
Total assets	$ 320,165	$ 253,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,509	$ 16,431
Accrued expenses and other liabilities	63,408	32,338
Current debt	23,725	25,607
Total current liabilities	101,642	74,376
Other long-term liabilities	2,563	2,903
Total liabilities	104,205	77,279
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,975,970 and 16,903,034 shares issued as of March 31, 2022 and December 31, 2021, respectively	17	17
Additional paid in capital	328,769	325,779
Accumulated other comprehensive income (loss)	418	(94)
Retained earnings	119,920	75,862
Treasury stock, at cost, 4,278,831 and 4,111,622 shares as of March 31, 2022 and December 31, 2021, respectively	(233,164)	(225,111)
Total stockholders' equity	215,960	176,453
Total liabilities and stockholders' equity	$ 320,165	$ 253,732

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Product sales, net	$ 90,088	$ 17,120
Royalty revenue	25,786	24,129
Total revenue	115,874	41,249
Operating expenses:		
Cost of product sales	25,176	8,442
Cost of royalty revenue	2,579	2,413
Research and development	6,108	14,288
Selling, general and administrative	22,182	19,879
Total operating expenses	56,045	45,022
Income (loss) from operations	59,829	(3,773)
Interest income	154	35
Interest expense	(366)	(422)
Other (expense) income	(1,957)	5,500

Total other (expense) income, net	(2,169)	5,113
Income before income tax provision	57,660	1,340
Income tax provision	(13,602)	(1,761)
Net income (loss)	$ 44,058	$ (421)
Earnings (loss) per share attributable to common stockholders:		
Basic	$ 3.47	$ (0.03)
Diluted	$ 3.41	$ (0.03)
Weighted average number of common shares outstanding:		
Basic	12,710,646	13,069,373
Diluted	12,906,811	13,069,373

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net income (loss)	$ 44,058	$ (421)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Deferred income taxes	(2,432)	902
Depreciation expense	177	190
Noncash operating lease expense related to right-of-use assets	290	252
Amortization expense of intangible assets	731	706
Fair value adjustments on equity investment	2,530	(5,600)
Stock-based compensation expense	4,295	6,508
Convertible promissory note related credit losses	36	100
Amortization of debt issuance costs	118	118
Fair value adjustments related to derivative instruments	(608)	—
Accretion of discount on convertible promissory note	(45)	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(89,710)	5,810
Inventories	(2,910)	1,213
Prepaid expenses and other current assets	(1,948)	(2,870)
Accounts payable	(1,651)	6,291
Accrued expenses and other liabilities	30,800	(2,403)
Other assets and other long-term liabilities, net	(342)	(318)
Net cash (used in) provided by operating activities	(16,611)	10,478
Cash flows from investing activities:		
Purchase of property and equipment	(168)	(384)
Purchase of convertible promissory note	—	(5,000)
Net cash used in investing activities	(168)	(5,384)
Cash flows from financing activities:		
Proceeds from common stock option exercises	—	1,963
Employee withholding taxes related to stock-based awards	(1,305)	(1,551)
Payment of debt	(2,000)	(2,000)
Repurchases of common stock	(8,053)	(1,432)
Net cash used in financing activities	(11,358)	(3,020)
Net (decrease) increase in cash and cash equivalents	(28,137)	2,074
Cash and cash equivalents at beginning of period	97,659	103,155
Cash and cash equivalents at end of period	$ 69,522	$ 105,229
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 41	$ 267
Interest	265	321

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP NET INCOME AND
ADJUSTED NON-GAAP EARNINGS PER SHARE (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Net income (loss) - GAAP	$ 44,058	$ (421)
Adjustments:		
Cost of product revenues:		
Amortization expense	731	301
Research and development:		
Stock-based compensation expense	643	895
Depreciation expense	48	53
Severance	—	274
Selling, general and administrative:		
Stock-based compensation expense	3,652	5,613
Amortization expense	—	405
Depreciation expense	129	137
Severance	49	306
Acquisition related costs	1,490	—
Legal settlement	300	—
Other:		
Non-cash interest expense	118	118
Fair value adjustments on equity investment	2,530	(5,600)
Convertible promissory note related credit losses	36	—
Fair value adjustments related to derivative instruments	(608)	—
Accretion of discount on convertible promissory note	(45)	—
Tax effect of the non-GAAP adjustments	(979)	1,086
Adjusted non-GAAP net income	$ 52,152	$ 3,167
Adjusted non-GAAP earnings per share:		
Basic	$ 4.10	$ 0.24
Diluted	$ 4.04	$ 0.24
Weighted number of common shares outstanding:		
Basic	12,710,646	13,069,373
Diluted	12,906,811	13,276,283

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP EBITDA (UNAUDITED)
(In thousands)

	Three Months Ended March 31,		Twelve Months Ended March 31,	Twelve Months Ended December 31,
	2022	**2021**	**2022**	**2021**
Net income (loss) - GAAP	$ 44,058	$ (421)	$ 35,852	$ (8,627)
Add back:				
Interest expense, net of interest income	212	387	900	1,075
Income tax provision	13,602	1,761	15,920	4,079
Depreciation and amortization expense	908	896	3,772	3,760
Add back:				
Stock-based compensation expense	4,295	6,508	17,342	19,555
Fair value adjustments on equity investment	2,530	(5,600)	14,300	6,170
Expense of acquired in-process research & development	—	—	15,339	15,339
Convertible promissory note related credit losses	36	—	794	758

Fair value adjustments related to derivative instruments	(608)	—	(1,294)	(686)
Severance	49	580	1,553	2,084
Legal settlement	300	—	300	—
Acquisition related costs	1,490	—	1,490	—
Adjusted Non-GAAP EBITDA	$ 66,872	$ 4,111	$ 106,268	$ 43,507

Important Safety Information for BYFAVO™ (remimazolam) Injection

Indications

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.**

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (e.g., opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA-PS class III or IV patients.

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, and anaphylaxis. BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) in the neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life but may extend out to approximately 3 years of age in humans.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (total dose) and undergoing colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and labor for signs of sedation and respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours after BYFAVO administration.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in patients less than 18 years of age.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, there is a potential for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supplemental doses of BYFAVO slowly to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for the procedure. All patients should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential for abuse and physical dependence.

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* Adjusted non-GAAP net income, adjusted non-GAAP earnings per share, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense are non-GAAP financial measures. For descriptions and reconciliations of these non-GAAP financial measures to their most comparable GAAP financial measures, please see below and the tables at the end of this press release.

Adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense do not account for any impacts that may result from the Company's proposed acquisition of Acacia Pharma Group plc.

[1] https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf