AcelRx Pharmaceuticals Reports First Quarter 2020 Financial Results

May 11, 2020

Expects to See Strong Volume of Orders from U.S. Military Following Milestone C Approval for DSUVIA
Provides Updates on Tetraphase Transaction

REDWOOD CITY, Calif., May 11, 2020 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today reported its first quarter 2020 financial results.

"During this unprecedented time, I am proud of the commitment demonstrated by our employees as we continue making progress towards our year-end strategic and operational 2020 goals," said Vince Angotti, Chief Executive Officer of AcelRx. "The Milestone C approval for DSUVIA® in April was a significant catalyst for the Company and validates DSUVIA's key role in modernizing the treatment of acute pain. We expect to see a strong volume of orders from the U.S. Army beginning later this year and into the future. The approval also opens doors to other branches of the military, additional areas of the Federal government, and to state governments and agencies. Specifically, we expect the next step with the Department of Defense will be DSUVIA's inclusion on the Joint Deployment Formulary. We are pleased with the swift integration of our commercial team with Tetraphase under our co-promotion agreement, which we believe will benefit both companies moving forward."

First Quarter and Recent Highlights

- DSUVIA achieved Milestone C approval from the Department of Defense, a decision that approves DSUVIA for use in all U.S. Army sets, kits and outfits (SKOs) with an expectation of expanded use across all branches of the military and the potential for use across additional federal and state agencies. AcelRx expects that initial stocking orders beginning later this year for U.S. Army SKOs alone will approximate $30 million over the next three years based on troop deployment schedules.
- Prior to the impact from the COVID-19 pandemic, AcelRx was on pace to exceed formulary approvals and REMS-certified facilities goals for 2020. Following the initial impact of COVID, as of April 30, 2020, 221 healthcare facilities are now REMS-certified and able to purchase DSUVIA and 223 formulary approvals have been achieved. As previously communicated, in response to the COVID-19 pandemic, hospitals and ambulatory surgery centers have restricted in-person meetings with pharmaceutical company personnel. Accordingly, year-end 2020 REMS-certified facilities and formulary approvals goals will be re-evaluated once COVID-19 restrictions are lifted and there is greater visibility into healthcare facility access.
- Expect the publication of two hospital studies of real-world data of DSUVIA in the perioperative setting which analyze DSUVIA's impact on IV opioid requirements in the post-anesthesia care unit (PACU) and discharge time from the PACU in the coming months.
- Announced an agreement with Brigham and Women's Hospital for an investigator-initiated study of DSUVIA led by Richard D. Urman MD, MBA, Associate Professor of Anesthesia and co-director of the Center for Perioperative Research at Brigham and Women's Hospital and Harvard Medical School. The study plans to examine the perioperative use of DSUVIA in the analgesic regimen for spine surgery.

Financial Information

- As previously announced:
  - Cash, cash equivalents and short-term investments balance of $52.7 million as of March 31, 2020;
  - First quarter 2020 net revenues were $0.4 million;
  - Combined R&D and SG&A expenses for the first quarter of 2020 totaled $14.7 million compared to $11.4 million for the first quarter of 2019. Excluding stock-based compensation expense, these amounts were $13.6 million for the first quarter of 2020 compared to $10.3 million for the first quarter of 2019. The increase in combined R&D and SG&A expenses is primarily due to business development costs related to the proposed acquisition of Tetraphase and increased personnel-related expenses for the commercial launch of DSUVIA. See the "Reconciliation of Non-GAAP Financial Measures" table below for a reconciliation of the non-GAAP operating expenses described above to their related GAAP measures.
- For the first quarter of 2020, net loss was $15.9 million, or $0.20 per basic and diluted share, compared to $13.7 million, or $0.17 per basic and diluted share, for the first quarter of 2019.

Tetraphase Transaction Update

On March 15, 2020, AcelRx entered into a definitive agreement (the Merger Agreement) to acquire Tetraphase Pharmaceuticals, Inc. (Tetraphase) and a co-promotion agreement with Tetraphase. Training of both the AcelRx and Tetraphase teams is complete and co-promotion efforts for DSUVIA and XERAVA ™ are underway.

AcelRx is aware of the May 8, 2020 disclosure by Tetraphase indicating it received a competing acquisition proposal from La Jolla Pharmaceutical Company (La Jolla) that the Tetraphase board of directors (Tetraphase Board) believes constitutes or could reasonably be expected to lead to a superior offer. The Tetraphase Board also stated that it continued to recommend the AcelRx merger and has not made any recommendations with respect to the other competing acquisition proposal by La Jolla. Our understanding is as follows:

- The La Jolla proposal is for an upfront value of $22 million, payable in cash, inclusive of an estimate of approximately $11.9 million in Black-Scholes consideration due to select warrant holders and approximately $10.1 million for Tetraphase common equity holders (an implied price per share of $0.93), and contingent value rights of up to $12.5 million.
- This compares to the AcelRx proposal for an upfront value of approximately $21.7 million payable in stock, based on the closing price of AcelRx stock on May 8th, inclusive of an estimate of approximately $11.8 million in Black-Scholes consideration due to select warrant holders and approximately $9.9 million for Tetraphase common equity holders (an implied price per share of $0.92), and contingent value rights of up to $12.5 million.

Under the Merger Agreement with Tetraphase, should the Tetraphase Board indicate that it intends to change its recommendation in favor of the Merger Agreement, AcelRx would have the opportunity to respond within a specified time period.

Regardless of whether the Tetraphase Board ultimately chooses to accept an offer (including the La Jolla offer) other than the AcelRx transaction under the Merger Agreement, the co-promotion agreement between the two companies would remain in place – safeguarded by significant financial obligations. If a party other than AcelRx ultimately combines with Tetraphase, they will promote DSUVIA and AcelRx will continue to promote XERAVA. AcelRx will provide additional updates to its stockholders regarding Tetraphase at the appropriate time.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, May 11, 2020 at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is accessible by visiting the Investors page of AcelRx's website at www.acelrx.com and clicking on the webcast link. The webcast will be accompanied by a slide presentation. Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor page of AcelRx's website at www.acelrx.com.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO™ irEurope, approved by the FDA in November 2018, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration. The European Commission approved DZUVEO for marketing in Europe in June 2018 and AcelRx is currently in discussions with potential European marketing partners.

This release is intended for investors only. For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. AcelRx has one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO ™ in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

Non-GAAP Financial Measures
To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), AcelRx uses certain non-GAAP financial measures in this press release, in particular, excluding stock-based compensation expense from its operating expenses. AcelRx believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, AcelRx believes that these non-GAAP financial measures, when considered together with AcelRx's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare AcelRx's results from period to period and to its forward-looking guidance. In addition, these types of non-GAAP financial measures are regularly used by investors and analysts to model and track AcelRx's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate AcelRx's business and to make operating decisions. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with AcelRx's consolidated financial statements prepared in accordance with GAAP. The non-GAAP financial measures in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to anticipated procurement by the military, the expected closing and timing and the likelihood of the Tetraphase acquisition, expected benefits from the acquisition of Tetraphase and the co-promotion agreement, and ongoing effects and anticipated impacts to AcelRx's business as a result of the COVID-19 pandemic. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including the risk that AcelRx may not be able to close the acquisition of Tetraphase or achieve the expected benefits and cost synergies from the transactions, including through actions taken by competing bidders for Tetraphase, that there may be changes in estimated cash position based on the completion of AcelRx's financial statement closing procedures and the review by AcelRx's independent registered public accounting firm of such financial statements, that potential sales volumes to the Department of Defense may not materialize, or that the impacts AcelRx is experiencing from the ongoing COVID-19 pandemic may be prolonged or exacerbated. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described in AcelRx's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC.

AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

Additional Information and Where to Find It

In connection with the proposed transaction between AcelRx and Tetraphase, AcelRx filed with the SEC a registration statement on Form S-4 (No. 333-237584) (the Registration Statement) containing a document constituting a prospectus of AcelRx and a proxy statement of Tetraphase. The Registration Statement was declared effective by the SEC on April 24, 2020, and Tetraphase mailed the definitive proxy statement/prospectus to stockholders of Tetraphase on or about April 28, 2020. AcelRx and Tetraphase also plan to file other relevant documents with the SEC regarding the transaction. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT/PROSPECTUS AND OTHER RELEVANT DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of the Registration Statement and the definitive proxy statement/prospectus and other relevant documents filed or that will be filed by AcelRx or Tetraphase with the SEC through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed with the SEC by AcelRx will be available free of charge within the Investors section of AcelRx's website at http://ir.acelrx.com. Copies of the documents filed with the SEC by Tetraphase will be available free of charge within the Investors section of Tetraphase's website at https://ir.tphase.com/investor-relations.

Participants in the Solicitation

Each of AcelRx and Tetraphase and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from Tetraphase stockholders in connection with the proposed transaction. Information about AcelRx's directors and executive officers is included in the definitive proxy statement for its 2020 annual meeting of stockholders, which was filed with the SEC on April 24, 2020. Information about Tetraphase's directors and executive officers is included in Tetraphase's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which was filed with the SEC on March 12, 2020. Other information regarding the participants in the solicitation of proxies in connection with the proposed transaction and a description of their direct and indirect interests, by security holdings or otherwise, is contained in the definitive proxy statement/prospectus filed with the SEC on April 24, 2020. When available, investors may obtain free copies of these documents from AcelRx or Tetraphase as indicated above.

No Offer or Solicitation

This communication is being made in respect of the proposed transaction involving AcelRx and Tetraphase. This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31	
	2020	**2019**
Statement of Comprehensive Loss Data		
Revenue:		
Product sales	$ 274	$ 126
Contract and other collaboration	112	139
Total revenue	386	265
Operating costs and expenses:		
Cost of goods sold (1)	1,511	1,230
Research and development (1)	1,412	1,377
Selling, general and administrative (1)	13,311	9,976
Total operating costs and expenses	16,234	12,583
Loss from operations	(15,848)	(12,318)
Other income (expense):		
Interest expense	(855)	(376)
Interest income and other income (expense), net	(65)	627
Non-cash interest income (expense) on liability related to sale of future royalties	843	(1,607)
Total other income (expense)	(77)	(1,356)
Net loss	$ (15,925)	$ (13,674)
Basic and diluted net loss per common share	$ (0.20)	$ (0.17)
Shares used in computing basic and diluted net loss per common share	80,057	78,789

(1) Includes the following non-cash, stock-based compensation expense:

Cost of goods sold	$ 46	$ 61
Research and development	200	224
Selling, general and administrative	900	822
Total	$ 1,146	$ 1,107

	March 31, 2020	December 31, 2019
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 52,725	$ 66,137
Total assets	77,339	91,356
Total liabilities	132,620	132,774
Total stockholders' (deficit) equity	(55,281)	(41,418)

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less associated stock-based compensation expense)

	Three Months Ended March 31	
	2020	**2019**
Operating expenses (GAAP):		
Research and development	$ 1,412	$ 1,377
Selling, general and administrative	13,311	9,976
Total operating expenses	14,723	11,353
Less associated stock-based compensation expense	1,100	1,046
Operating expenses (non-GAAP)	$ 13,623	$ 10,307

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