NEWS RELEASE

Acceleron Reports Third Quarter 2021 Financial Results

11/4/2021

- Acceleron recognized approximately $32.0 million in royalty revenue for Q3 2021 from approximately $160 million in net sales of REBLOZYL® (luspatercept-aamt) -

- Three clinical abstracts on REBLOZYL have been accepted for presentation at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition scheduled for December 11 to 14, 2021 -

- Previously announced agreement for Acceleron to be acquired by Merck; transaction expected to close in Q4 2021 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Acceleron Pharma Inc. (Nasdaq:XLRN), a biopharmaceutical company dedicated to the discovery, development, and commercialization of TGF-beta superfamily therapeutics to treat serious and rare diseases, today reported financial results for the third quarter ended September 30, 2021.

Corporate Highlights

- On September 30, Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Acceleron Pharma Inc. announced that the companies entered into a definitive agreement under which Merck, through a subsidiary, will acquire Acceleron for $180 per share in cash for an approximate total equity value of $11.5 billion.

Program Highlights

Pulmonary

Sotatercept: Pulmonary Hypertension

Sotatercept acts as an investigational reverse-remodeling agent proposed to rebalance TGF-beta superfamily

signaling. In preclinical models of pulmonary arterial hypertension (PAH), sotatercept reversed pulmonary arterial wall and right ventricular remodeling that are hallmarks of the disease.

- Enrollment remains ongoing in the STELLAR Phase 3 trial of sotatercept in patients with PAH.
- In August, Acceleron initiated the HYPERION Phase 3 trial of sotatercept in newly diagnosed patients with intermediate- and high-risk PAH.
- The Company recently initiated the ZENITH Phase 3 trial of sotatercept in patients with WHO functional class III or IV PAH at high risk of mortality.
- Study start up activities are underway for the CADENCE Phase 2 trial of sotatercept in patients with pulmonary hypertension due to left heart disease.

ACE-1334: Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)

ACE-1334 is an Acceleron-discovered, TGF-beta superfamily-based ligand trap designed to bind and inhibit TGF-beta 1 and 3 ligands but not TGF-beta 2. ACE-1334 has shown robust anti-fibrotic activity in multiple preclinical models of fibrosis.

- In October, Acceleron initiated a Phase 1b study to evaluate the activity of ACE-1334 in patients with SSc-ILD.

Hematology

REBLOZYL (luspatercept-aamt):

REBLOZYL is the first and only erythroid maturation agent approved in the United States, Europe, and Canada designed to promote late-stage red blood cell (RBC) production. REBLOZYL is part of the global collaboration between Acceleron and Bristol Myers Squibb.

- Acceleron recognized approximately $32.0 million in royalty revenue from approximately $160 million in net sales of REBLOZYL in the third quarter of 2021. This compares with approximately $25.6 million in royalty revenue from approximately $128 million in net sales of REBLOZYL in the second quarter of 2021.
    - Net sales of REBLOZYL for the third quarter include approximately $20 million to $25 million of sales from an inventory build due to the transition to wholesaler distribution and approximately $13.5 million of net sales outside of the United States.
- In September, the United States Food and Drug Administration granted luspatercept Orphan Drug designation for the treatment of anemia in patients with alpha-thalassemia.
- Enrollment remains ongoing in the COMMANDS Phase 3 trial in patients with first-line lower-risk MDS.
- Enrollment remains ongoing in the INDEPENDENCE Phase 3 trial in patients with anemia-associated with

myelofibrosis.

- Three clinical abstracts on REBLOZYL have been accepted for presentation at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition scheduled for December 11 to 14, 2021.

Financial Results

- Cash Position -Cash, cash equivalents and investments as of September 30, 2021 were $652.5 million, compared with $857.5 million as of December 31, 2020. Based on Acceleron's current operating plan and projections, the Company believes that its current cash, cash equivalents and investments, along with the expected royalty revenue from REBLOZYL sales, will be sufficient to fund the Company's projected operating requirements for the foreseeable future.
- Revenue - Revenue for the third quarter of 2021 was $34.2 million, which includes $2.2 million of cost share revenue and $32.0 million of royalty revenue from net sales of REBLOZYL. All revenue was derived from the Company's partnership with Bristol Myers Squibb.
- R&D Expenses - GAAP R&D expenses were $59.7 million for the third quarter of 2021. Non-GAAP R&D expenses were $53.1 million for the third quarter of 2021, excluding $5.6 million and $1.0 million in non-cash, stock-based compensation and depreciation and amortization expense, respectively.
- SG&A Expenses - GAAP SG&A expenses were $45.1 million for the third quarter of 2021. Non-GAAP SG&A expenses were $39.1 million for the third quarter of 2021, excluding $5.8 million and $0.1 million in non-cash, stock-based compensation and depreciation and amortization expense, respectively.
- Net Loss - The Company's GAAP net loss for the third quarter of 2021 was $70.5 million, or $1.16 per share. Non-GAAP adjusted net loss for the third quarter was $57.9 million, or $0.95 per share, excluding $11.4 million and $1.2 million in non-cash, stock-based compensation and depreciation and amortization expense, respectively.

Non-GAAP Financial Measures

Acceleron supplements its results of operations prepared in accordance with U.S. generally accepted accounting principles, or GAAP, with certain non-GAAP financial measures, including non-GAAP R&D expense, non-GAAP SG&A expense, adjusted net loss and adjusted net loss per share, that exclude stock-based compensation expense and depreciation and amortization expense. These results should not be viewed as a substitute for the Company's GAAP results and are provided as a complement to results provided in accordance with GAAP. Management believes these non-GAAP financial measures provide investors with additional insight into underlying trends of the Company's ongoing business, and are important in comparing current results with prior period results. Investors are cautioned that there are material limitations associated with the use of non-GAAP financial measures. In addition, other companies may report similarly titled non-GAAP measures, but calculate them differently, which reduces their usefulness as a comparative measure. In the reconciliation tables below, Acceleron presents these

non-GAAP financial measures reconciled to their comparable GAAP financial measures.

Conference Call and Webcast

The Company will not be holding a quarterly earnings call or webcast.

About Acceleron

Acceleron is a biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. Acceleron's leadership in the understanding of TGF-beta superfamily biology and protein engineering generates innovative compounds that engage the body's ability to regulate cellular growth and repair.

Acceleron focuses its research, development, and commercialization efforts in pulmonary and hematologic diseases. In pulmonary, Acceleron is developing sotatercept for the treatment of pulmonary hypertension (PH). Following positive PULSAR Phase 2 results, Acceleron is executing on its Phase 3 development plan to support its long-term vision of establishing sotatercept as a backbone therapy for patients with pulmonary arterial hypertension (PAH) at all stages of the disease. Acceleron is also expanding the development of sotatercept into Group 2 PH, with the CADENCE Phase 2 trial expected to initiate this year. Acceleron has expanded its rare pulmonary disease pipeline and is investigating the potential of ACE-1334 in a Phase 1b/Phase 2 trial in systemic sclerosis-associated interstitial lung disease (SSc-ILD).

In hematology, REBLOZYL® (luspatercept-aamt) is the first and only erythroid maturation agent approved in the United States, Europe, and Canada for the treatment of anemia in certain blood disorders. REBLOZYL is part of a global collaboration partnership with Bristol Myers Squibb. The Companies co-promote REBLOZYL in the United States and are also developing luspatercept for the treatment of anemia in patient populations of myelodysplastic syndromes, beta-thalassemia, and myelofibrosis.

For more information, please visit **www.acceleronpharma.com**. Follow Acceleron on Social Media: **@AcceleronPharma** and **LinkedIn**.

ACCELERON PHARMA INC.
CONDENSED CONSOLIDATED BALANCE SHEET
(Amounts in thousands)
(unaudited)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 336,456	$ 670,952
Short and long-term investments	316,063	186,536
Operating lease - right of use asset, net	18,310	21,988
Other assets	117,019	52,861

Total assets	$ 787,848	$ 932,337
Operating lease liability - right of use, short-term and long-term	$ 20,114	$ 24,077
Other liabilities	49,581	53,153
Total liabilities	69,695	77,230
Total stockholders' equity	718,153	855,107
Total liabilities and stockholders' equity	$ 787,848	$ 932,337

ACCELERON PHARMA INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	$ 34,199	$ 22,561	$ 86,897	$ 66,656
Costs and expenses:				
Research and development	59,717	40,747	173,146	116,663
Selling, general and administrative	45,112	21,042	111,646	59,705
Total costs and expenses	104,829	61,789	284,792	176,368
Loss from operations	(70,630)	(39,228)	(197,895)	(109,712)
Other income (expense), net	180	(6)	466	1,108
Loss before income taxes	(70,450)	(39,234)	(197,429)	(108,604)
Income tax provision	(15)	(11)	(28)	(31)
Net loss	$ (70,465)	$ (39,245)	$ (197,457)	$ (108,635)
Net loss per share- basic and diluted	$ (1.16)	$ (0.66)	$ (3.25)	$ (1.95)
Weighted-average number of common shares used in computing net loss per share- basic and diluted	60,937	59,640	60,748	55,635

ACCELERON PHARMA INC.
RECONCILIATION OF GAAP TO NON-GAAP COSTS and EXPENSES
(Amounts in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP research and development	$ 59,717	$ 40,747	$ 173,146	$ 116,663
Less adjustments:				
Stock-based compensation	5,586	3,794	19,615	10,194
Depreciation and amortization	1,023	827	2,894	2,630
Non-GAAP research and development	$ 53,108	$ 36,126	$ 150,637	$ 103,839
GAAP selling, general and administrative	$ 45,112	$ 21,042	$ 111,646	$ 59,705
Less adjustments:				
Stock-based compensation	5,835	4,192	20,911	11,611
Depreciation and amortization	138	76	328	211
Non-GAAP selling, general and administrative	$ 39,139	$ 16,774	$ 90,407	$ 47,883

ACCELERON PHARMA INC.
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP NET LOSS AND NET LOSS PER SHARE
(Amounts in thousands except per share data)
(unaudited)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2021	2020	2021	2020
GAAP net loss	$ (70,465)	$ (39,245)	$ (197,457)	$ (108,635)
Adjustments:				
Stock-based compensation	11,421	7,986	40,526	21,805
Depreciation and amortization	1,160	903	3,222	2,841
Adjusted net loss (non-GAAP)	$ (57,884)	$ (30,356)	$ (153,709)	$ (83,989)
GAAP net loss per share- basic and diluted	$ (1.16)	$ (0.66)	$ (3.25)	$ (1.95)
Adjustments:				
Stock-based compensation	0.19	0.13	0.67	0.39
Depreciation and amortization	0.02	0.02	0.05	0.05
Adjusted net loss per share (non-GAAP)	$ (0.95)	$ (0.51)	$ (2.53)	$ (1.51)
Weighted-average number of common shares used in computing net loss per share	60,937	59,640	60,748	55,635

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements about the Company's strategy, future plans and prospects, including statements regarding the development and commercialization of the Company's compounds, the timeline for clinical development and regulatory approval of the Company's compounds, the expected timing for reporting of data from ongoing clinical trials, the anticipated timing of the closing of the proposed transaction with Merck, the Company's future cash position and the potential of REBLOZYL® (luspatercept-aamt) as a therapeutic drug. The words "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Actual results could differ materially from those included in the forward-looking statements due to various factors, risks and uncertainties, including, but not limited to, that preclinical testing of the Company's compounds and data from clinical trials may not be predictive of the results or success of other clinical trials, that regulatory approval of the Company’s compounds in one indication or country may not be predictive of approval in another indication or country, that the development of the Company’s compounds may take longer and/or cost more than planned or accelerate faster than currently expected, that the Company or its collaboration partner, Bristol Myers Squibb Company (“BMS”), may be unable to successfully complete the clinical development of the Company’s compounds, that the Company or BMS may be delayed in initiating, enrolling or completing any clinical trials, that the Company’s compounds may not receive regulatory approval or become commercially successful products, and that the closing of the proposed transaction with Merck is subject to a series of conditions, including with respect to required competition clearances, which may take longer than is currently anticipated to be satisfied, and may not be satisfied. These and other risks and uncertainties are identified under the heading “Risk Factors” included in the Company’s most recent Annual Report on Form 10-K and other filings that the Company has made and may make with the SEC in the future.

The forward-looking statements contained in this press release are based on management's current views, plans, estimates, assumptions, and projections with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

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