



Novus Therapeutics Reports Third Quarter 2020 Financial Results

November 16, 2020

Company to host conference call and webcast at 4:30pm ET today

IRVINE, Calif.--(BUSINESS WIRE)--Nov. 16, 2020-- Novus Therapeutics, Inc. ("Novus") (NASDAQ: NVUS), a clinical stage biopharmaceutical company focused on developing life-changing, targeted medicines for patients undergoing organ or cellular transplantation, as well as those living with immunological diseases, today reported its financial results for the quarter ended September 30, 2020, and operational highlights.

Recent Business Highlights

- Completed the acquisition of Anelixis Therapeutics, Inc., a privately held clinical stage biotechnology company developing a next generation anti-CD40 Ligand (CD40L) antibody
- Completed a private placement financing expected to result in gross proceeds to Novus of approximately \$108 million before deducting placement agent and other offering expenses
- Commenced enrollment in a phase 2 clinical trial of AT-1501 in adults with amyotrophic lateral sclerosis (ALS) in October 2020

"During the quarter, we accomplished three key transformational objectives focused on increasing shareholder value," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Novus Therapeutics, Inc. "First, we acquired a potential best in class asset, Anelixis' AT-1501 anti-CD40L antibody, a well-validated target with broad therapeutic possibilities. Second, we financed Novus to have sufficient capital to execute up to four Phase 2 clinical trials with AT-1501 in different high-need indications. Third, we integrated the companies without losing momentum and were able to launch AT-1501's Phase 2 trial in adults with ALS as planned. We now have the scientific, organizational and financial resources to rapidly advance this asset in multiple other indications over the coming quarters, setting the stage for a catalyst-rich 2021."

Financial Results for the Three and Nine Months Ended September 30, 2020

The company reported a net loss of \$6.1 million, or \$5.51 per share, for the three months ended September 30, 2020, compared to a net loss of \$2.9 million, or \$4.01 per share, for the same period in 2019. The company reported a net loss of \$16.9 million, or \$16.81 per share, for the nine months ended September 30, 2020, compared to a net loss of \$11.9 million, or \$18.74 per share, for the same period in 2019.

R&D expenses were \$615,000 for the three months ended September 30, 2020, compared to \$1.5 million for the same period in 2019. The decrease in R&D expenses of \$894,000 was primarily due to decreases in clinical costs, formulation development costs, personnel costs, consulting services, and travel and meetings expenses. The decreases were partially offset by an increase in stock-based compensation expense. These decreases were made following the completion of our Phase 2a study of our legacy lead program in acute otitis media and the subsequent suspension of development activities as we assessed strategic options. We expect our research and development costs to increase in future periods as we proceed with the development of AT-1501.

G&A expenses were \$3.7 million for the three months ended September 30, 2020, compared to \$1.4 million for the same period in 2019. The increase in G&A expenses of \$2.3 million was primarily due to increases in merger related costs incurred in the third quarter, stock-based compensation, and general operating costs. The increases were partially offset by decreases in litigation costs, personnel costs, costs associated with operating a publicly traded company, and travel and meetings expenses due to the ongoing pandemic. Following the completion of Anelixis acquisition, we expect our general and administrative expenses to increase in future periods, as we have a larger headcount and incur expenses relating to the development of a larger product pipeline.

R&D expenses were \$3.1 million for the nine months ended September 30, 2020, compared to \$6.8 million for the same period in 2019. The decrease in R&D expenses of \$3.7 million was primarily due to decreases in clinical costs, formulation development costs, personnel costs, consulting services, travel and meetings expenses and other development costs. The decreases were partially offset by an increase in stock-based compensation expense. These decreases were made following the completion of our Phase 2a study of our legacy lead program in acute otitis media and the subsequent suspension of development activities as we assess strategic options. We expect our research and development costs to increase in future periods as we proceed with the development of AT-1501.

G&A expenses were \$6.7 million for the nine months ended September 30, 2020, compared to \$5.1 million for the same period in 2019. The increase in G&A expenses of \$1.6 million was primarily due to increases in merger related costs, stock-based compensation, and general operating costs. The increases were partially offset by decreases in litigation costs, costs associated with operating a publicly traded company, personnel costs, and travel and meetings expenses due to the ongoing pandemic. Following the completion of Anelixis acquisition, we expect our general and administrative expenses to increase in future periods, as we have a larger headcount and incur expenses relating to the development of a larger product pipeline.

During the period, the company recognized \$2.3 million in restructuring expenses.

The company had \$114.5 million in cash and cash equivalents as of September 30, 2020, compared to \$8.8 million as of December 31, 2019.

Conference Call & Webcast

4:30 PM Eastern Time / 1:30 PM Pacific Time

Toll Free: 877-407-3982

International: 201-493-6780

Conference ID: 13713171

Webcast: <http://public.viavid.com/index.php?id=142451>

About AT-1501

AT-1501 is a humanized IgG1 anti-CD40L antibody with high affinity for CD40L, a well-validated target with broad therapeutic potential. The CD40/CD40L pathway plays a central role in generating pro-inflammatory responses in autoimmune disease, allograft transplant rejection, and neuroinflammation. In a Phase 1 safety study of healthy volunteers and adults with ALS, AT-1501 was well tolerated at all doses tested. AT-1501 previously received orphan drug designation from the U.S. Food and Drug Administration for the treatment of ALS.

About Novus Therapeutics

Novus Therapeutics, Inc. is a clinical stage biotechnology company using its expertise in targeting the CD40L pathway to develop potential treatments for people requiring an organ or cell-based transplant, and for people with living with immunological diseases. Novus is headquartered in Irvine, Calif. For more information, please visit the company's website at www.novustherapeutics.com.

Follow Novus Therapeutics on social media: [@Novus_Thera](#) and [LinkedIn](#).

Forward-Looking Statements

This press release contains forward-looking statements that involves substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding: risks related to market conditions; expectations regarding the timing for the commencement of future clinical trials; expectations regarding the success of clinical trials; the rate and degree of market acceptance and clinical utility of the company's products; the company's estimates regarding expenses and cash runway; and the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the SEC, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

View source version on businesswire.com:

NOVUS THERAPEUTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except share data)

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 114,464	\$ 8,791
Prepaid expenses and other current assets	637	1,180
Total current assets	115,101	9,971
Property and equipment, net	—	5
Operating lease asset, net	183	316
Goodwill	44,466	—
In-process research and development	32,386	—
Other assets	449	639
Total assets	\$ 192,585	\$ 10,931
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 758	\$ 329
Current operating lease liability	191	180
Accrued severance	803	—
Accrued expenses and other liabilities	4,378	813
Total current liabilities	6,130	1,322
Non-current operating lease liability	—	144
Total liabilities	6,130	1,466
Commitments and contingencies (Note 5)		
Series X ¹ non-voting convertible preferred stock, \$0.001 par value, 515,000 shares authorized; 339,138 and no shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	164,949	—
Stockholders' equity:		
Series X preferred stock, \$0.001 par value, 10,000 shares authorized; 511 and no shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 1,274,631 and 720,408 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	95,994	67,046

Accumulated deficit	(74,489)	(57,582)
Total stockholders' equity	21,506	9,465
Total liabilities, convertible preferred stock and stockholders' equity	\$ 192,585	\$ 10,931

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 615	\$ 1,509	\$ 3,095	\$ 6,795
General and administrative	3,731	1,411	6,730	5,089
Restructuring expense	1,802	—	2,292	—
Total operating expenses	6,148	2,920	12,117	11,884
Loss from operations	(6,148)	(2,920)	(12,117)	(11,884)
Other income, net	4	27	39	17
Warrant inducement expense	—	—	(4,829)	—
Net loss and comprehensive loss	\$ (6,144)	\$ (2,893)	\$ (16,907)	\$ (11,867)
Net loss per share, basic and diluted	\$ (5.51)	\$ (4.01)	\$ (16.81)	\$ (18.74)
Weighted-average common shares outstanding, basic and diluted	1,114,133	720,829	1,006,008	633,187

View source version on [businesswire.com](https://www.businesswire.com/news/home/20201116005994/en/): <https://www.businesswire.com/news/home/20201116005994/en/>

Media:

Amanda Sellers
asellers@vergescientific.com
301.332.5574

Investors:

Bruce Mackle
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com
929.469.3859

Source: Novus Therapeutics, Inc.