Novan Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 12, 2021

– Positive data across all three of the Company's priority pipeline development programs, announced in Q2 2021, further validating the potential of its novel, proprietary NITRICIL™ technology –

– Preparation underway for the Company's first New Drug Application filing for lead program, SB206, following the statistically significant topline efficacy results from pivotal Phase 3 trial in patients with molluscum contagiosum –

– Ongoing exploration of opportunities for pipeline expansion and clinical development, leveraging internal expertise and strategic partnerships –

– Company to host update conference call and webcast today at 8:30 a.m. ET –

DURHAM, N.C., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced its financial and operating results for the quarter ended June 30, 2021 and provided a corporate update. The Company will host a conference call and webcast, today, August 12, 2021, at 8:30 a.m. ET (details below).

"The second quarter of 2021 has been truly transformative, and nothing short of exciting for Novan. We have successfully demonstrated the potential of our NITRICIL™ platform technology with positive data readouts across all three of our priority development pipeline candidates. We have strengthened our cash position and ability to fund operations and provide optionality with our recently completed $40.0 million public offering. Importantly, we have well-positioned the Company to build value and potentially bring to market our first product, SB206, to provide patients with much-needed treatment benefit," commented Paula Brown Stafford, President and Chief Executive Officer of Novan.

Recent Highlights

- Ended the second quarter of 2021 with a total cash and cash equivalents balance of $65.8 million and positive working capital of $57.2 million;
- Announced that the final patient completed their last planned Week-24 visit in the B-SIMPLE4 pivotal Phase 3 trial for SB206 as a treatment for molluscum contagiosum ("molluscum");
- Completed a $40.0 million public offering of common stock;
- Reported positive topline efficacy and favorable safety data at Week-12 with primary endpoint achieving statistically significant results from pivotal Phase 3 trial of SB206 in patients with molluscum;
- Announced positive preclinical results evaluating berdazimer sodium in a SARS-CoV-2 transmission model in two independent trials of golden Syrian hamsters; and
- Further demonstrated the antimicrobial effect of NITRICIL™ platform technology against a wide variety of bacteria with positive *in vitro* results for NVN4100 in Companion Animal Health.

Development Pipeline Update

SB206 – A Topical Antiviral Treatment for Viral Skin Infections (Molluscum Contagiosum)

Novan is developing SB206 as a topical gel with anti-viral properties for the treatment of molluscum. SB206 has been most recently evaluated in a pivotal Phase 3 study, B-SIMPLE4. B-SIMPLE4 was a multi-center, double-blind, randomized, vehicle-controlled study that exceeded its enrollment target by randomizing 891 patients (1:1 randomization) in the study, across 55 clinical sites. Patients were treated for up to 12 weeks with a follow-up visit at Week 24. The primary endpoint for the study was the proportion of patients with complete clearance of all treatable molluscum lesions at Week 12 (Intent-to-Treat population, where the analysis assumes that patients with missing lesion counts at Week 12 are considered treatment failures).

In June 2021, the Company reported positive topline results, including statistical significance for the primary endpoint with a p-value of less than 0.0001. Additionally, as was consistent with results from the Company's Phase 2 and earlier Phase 3 studies, SB206 was found to be safe and well tolerated in the B-SIMPLE4 study. No treatment-related serious adverse events were reported. In July 2021, the Company announced that the last patient had completed their planned Week-24 follow-up visit in the B-SIMPLE4 pivotal Phase 3 clinical study. The planned follow-up visit at Week-24 was intended to further evaluate safety of SB206, 12 weeks following patient completion of treatment.

Upcoming Targeted Milestones:

- Full data readout from the B-SIMPLE4 study, including Week-24 safety follow-up, targeted in Q3 2021.
- Potential filing of a new drug application ("NDA") targeted no later than Q3 2022.

There are currently no U.S. Food and Drug Administration ("FDA") approved therapies for the treatment of molluscum. The Company believes that

SB206 as a topical, at-home, self or caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum.

For more information about the B-SIMPLE4 study, please visit clinicaltrials.gov and reference identifier: NCT04535531.

SB019 – Infectious Disease, Coronaviridae (COVID-19)

In June 2021, Novan announced positive preclinical results demonstrating efficacy of the Company's NITRICIL™ platform technology, berdazimer sodium (NVN1000), as an anti-viral therapy against SARS-CoV-2, the virus that causes COVID-19. To further evaluate the potential of its NITRICIL™ platform technology as an intranasal treatment option for COVID-19, the Company initiated preclinical *in vivo* studies evaluating the efficacy of berdazimer sodium to reduce viral burden in infected animals and to deter viral transmission to uninfected animals. The work was conducted at the Institute for Antiviral Research at Utah State University. Results from two separate studies independently demonstrated the ability of berdazimer sodium to prevent progression of infection into the lungs after transmission, significantly limiting severity of disease in this model. The intranasal treatment was well-tolerated during the preclinical *in vivo* studies, and no treatment-related adverse events were observed.

The Company observed a dose-dependent, statistically significant reduction ($P<0.0001$) in the amount of virus in the lungs of animals treated with berdazimer sodium concentrations as low as 2 mg/mL compared to placebo-treated controls. The effect was observed after co-habitation with infected hamsters who were also treated with berdazimer sodium. The average amount of virus in the lungs was reduced by greater than 4 logs (>99.99%) with more than half of the animals having no detectable virus in lung tissue at all.

Based on the scientific literature and the Company's previously reported *in vitro* and *in vivo* results, Novan believes that nitric oxide may inhibit viral replication by disrupting protein function that is critical for viral replication and infection through generation of reactive intermediates. The Company plans to submit a request to the FDA for guidance on an appropriate path for bringing a new potential treatment option to patients, as quickly as possible. The Company is evaluating its strategy to submit an Investigational New Drug application ("IND") for the purposes of advancing its SB019 product candidate, subject to regulatory guidance, successful completion of IND-enabling toxicology studies and obtaining additional financing or strategic partnering.

NVN4100 – Companion Animal Health

In June 2021, Novan announced positive proof-of-concept *in vitro* results and informative *in vivo* results with its new chemical entity, NVN4100, explored as a potential product candidate for topical antimicrobial indications in companion animal health.

Results from the *in vitro* assay demonstrated that NVN4100 had both inhibitory and bactericidal effects for a variety of pathogens. The tested pathogens include both antimicrobial resistant and antimicrobial susceptible strains of the most prevalent species associated with skin and ear conditions in animal health, including *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus pseudintermedius*, and *Staphylococcus schleiferi*.

Additionally, in collaboration with an independent third-party animal health research organization, Novan established a model of canine pyoderma, one of the most common skin conditions of dogs that is often resistant to first-line antimicrobials, to evaluate topically applied NVN4100 in an *in vivo* setting. The *in vivo* results suggest that the canine pyoderma model may serve as an appropriate tool to facilitate further development of NVN4100 as an alternative therapy to systemic and topical antimicrobials for the treatment of canine superficial pyoderma or other dermatology indications.

Based on the results to date and subject to the availability of funding, Novan intends to conduct additional studies and formulation work with NVN4100 to build a robust data set and engage with potential collaborators and strategic partners moving forward. The Company plans to disclose the full data set from the companion animal health exploratory studies at an upcoming scientific congress and/or in a peer-reviewed publication.

Financial Update

Summary of Financial Results for Second Quarter 2021

- Novan reported a net loss of $6.0 million for the three months ended June 30, 2021, compared to an $8.1 million net loss for the same period in 2020.
- As of June 30, 2021, Novan had a total cash and cash equivalents balance of $65.8 million and positive working capital of $57.2 million.
- The Company believes that its existing cash and cash equivalents balance as of June 30, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its operating needs into the first quarter of 2023, based on management's projections and planned operating and development activities described in the Company's quarterly report on Form 10-Q for the six month period ended June 30, 2021.

Summary of Financial Results for Year-to-Date June 2021

- Novan reported a net loss of $15.0 million for the six months ended June 30, 2021, compared to a $14.3 million net loss for the same period in 2020.
- License and collaboration revenue was $1.5 million for the six months ended June 30, 2021, compared to $2.1 million for the same period in 2020. The decrease from the prior year related to the change in the Company's estimated performance period related to the non-refundable upfront and expected milestone payments under one of the Company's license agreements, which was extended during the fourth quarter of 2020.
- Research and development expenses were $11.7 million for the six months ended June 30, 2021, compared to $8.7 million for the same period in 2020. The increase was primarily attributable to (i) net increased costs of $5.2 million related to

Novan's ongoing conduct and treatment phase activities of the B-SIMPLE4 Phase 3 trial during the first six months of 2021, compared to the relatively lower cost of wind down activities for its B-SIMPLE1 and B-SIMPLE2 Phase 3 trials during the comparative period in 2020; partially offset by (ii) a decrease of $1.9 million in other research and development expenses; and (iii) a $0.2 million decrease in costs related to the SB414 program. The decrease in other research and development expenses was primarily related to a $1.4 million decrease in research and development personnel costs, driven by (i) a $0.4 million decrease in non-cash compensation expense related to the change in the fair value of the Company's Tangible Stockholder Return Plan; (ii) a $0.4 million decrease in non-cash compensation expense associated with stock option compensation; (iii) a $0.4 million decrease in discrete severance charges and retention incentive compensation associated with business realignment and personnel reduction actions taken during the first quarter of 2020; and (iv) a $0.2 million decrease in recurring salary and benefits costs due to a reduced number of research and development personnel between the two comparative periods.

- General and administrative expenses were $5.1 million for the six months ended June 30, 2021, compared to $5.7 million for the same period in 2020. The decrease was primarily due to $0.8 million of non-cash expense recognized in the second quarter of 2020 related to the issuance of commitment shares in consideration for entering into the June 2020 Aspire Common Stock Purchase Agreement.

- Other income (expense), net was $0.4 million income for the six months ended June 30, 2021, compared to $0.1 million income for the six months ended June 30, 2020. During the second quarter of 2021, the Company recognized a $1.0 million gain on debt extinguishment related to the forgiveness of its Paycheck Protection Program loan in June 2021. This gain was partially offset by $0.6 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to one of the Company's license agreements.

Conference Call and Webcast

Novan management will host a conference call and webcast presentation for investors, analysts, and other interested parties today, Thursday, August 12, 2021, at 8:30 a.m. ET.

Interested participants and investors may access the conference call by dialing (844) 707-0661 (domestic) or (703) 318-2240 (international) and referencing conference ID: 6686508. The live webcast will be accessible on the Events page of the Investors section of the Novan website, novan.com, and will be archived for 90 days.

About Novan

Novan, Inc. is a late clinical-stage biotechnology company focused on leveraging its proprietary nitric oxide (NO) based technology platform, NITRICIL™ to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications in dermatology, men's and women's health, infectious diseases, and various other medical conditions with significant unmet needs. The Company's lead product candidate is SB206, a topical gel with antiviral properties, for the treatment of molluscum. The Company believes that SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would address an important unmet medical need for the treatment of molluscum.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe," "expect," "target," "anticipate," "may," "plan," "potential," "will," and similar expressions, and are based on the Company's current beliefs and expectations. These forward-looking statements include, but are not limited to, statements related to the potential therapeutic value of the Company's NITRICIL™ platform technology, the Company's pharmaceutical development of nitric oxide-releasing product candidates, including SB206, the timing of follow-up safety results from B-SIMPLE4, the potential timing of an NDA submission for SB206, the Company's expected cash runway, the timing of anticipated results of the Company's preclinical development programs, and the Company's intention to partner with third parties. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from the Company's expectations, including, but not limited to, risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that the FDA will not agree with the Company's approach to a potential NDA submission, that the Company's product candidates may not be approved or that additional studies may be required for approval or other delays may occur, that the Company may not have sufficient quantities of drug substance and/or drug product to support regulatory submissions and that the Company may not obtain funding sufficient to complete the regulatory or development process; the Company's limited experience as a company in obtaining regulatory approvals and commercializing pharmaceutical products; risks and uncertainties in the Company's ongoing or future product development activities and preclinical studies, which may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of the Company's product candidates; any operational or other disruptions as a result of the COVID-19 pandemic; the Company's ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development or commercialization of the Company's product candidates; risks related to the manufacture of raw materials, including the Company's active pharmaceutical ingredient and drug product components utilized in clinical trial materials, including supply chain disruptions or delays, failure to transfer technology and processes to third parties effectively or failure of those third parties (or the Company in connection with the upfit of the Company's new facility) to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities; the Company's reliance on arrangements with third parties to support its operations and development efforts and the risk that such parties will not successfully carry out their contractual duties or meet expected deadlines; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the twelve months ended December 31, 2020, and in the Company's subsequent filings with the Securities and Exchange Commission. Such forward-looking statements speak only as of the date of this press release, and Novan disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

NOVAN, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
License and collaboration revenue	$ 747	$ 1,100	$ 1,494	$ 2,124
Government research contracts and grants revenue	—	221	72	410
Total revenue	747	1,321	1,566	2,534
Operating expenses:				
Research and development	5,257	3,761	11,675	8,677
General and administrative	2,431	3,232	5,117	5,739
Impairment loss on long-lived assets	114	2,421	114	2,421
Total operating expenses	7,802	9,414	16,906	16,837
Operating loss	(7,055)	(8,093)	(15,340)	(14,303)
Other income (expense), net:				
Interest income	3	10	6	45
Gain on debt extinguishment	956	—	956	—
Other income (expense)	73	(3)	(597)	5
Total other income (expense), net	1,032	7	365	50
Net loss and comprehensive loss	$ (6,023)	$ (8,086)	$ (14,975)	$ (14,253)
Net loss per share, basic and diluted	$ (0.39)	$ (1.00)	$ (0.98)	$ (2.42)
Weighted-average common shares outstanding, basic and diluted	15,570,290	8,060,317	15,288,156	5,882,352

NOVAN, INC.
Selected Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 65,802	$ 35,879
Total current assets	68,778	44,007
Total assets	79,716	46,829
Total current liabilities	11,605	8,700
Total liabilities	47,390	43,852
Total stockholders' equity	32,326	2,977
Total liabilities and stockholders' equity	$ 79,716	$ 46,829

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