UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 25, 2020

Immunovant, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

> 320 West 37th Street New York, NY

(Address of principal executive offices)

001-38906 (Commission File Number) 83-2771572 (IRS Employer Identification No.)

10018 (Zip Code)

Registrant's telephone number, including area code: (917) 580-3099

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, \$0.0001 par value per share	IMVT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company 🗵

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \boxtimes

Item 7.01 Regulation FD Disclosure.

On August 25, 2020, Immunovant, Inc. ("Immunovant") issued a press release and held a conference call announcing topline results from its ASCEND MG trial. A copy of the press release and the presentation discussed on the conference call are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission (the "SEC") made by Immunovant, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On August 25, 2020, Immunovant issued a press release announcing topline results from its ASCEND MG trial.

The ASCEND MG trial is a multi-center, randomized, placebo-controlled Phase 2a clinical trial designed to evaluate the safety, tolerability, pharmacodynamics, and efficacy of IMVT-1401 in patients with moderate-to-severe generalized myasthenia gravis ("MG"). Results from thesix-week treatment period included three arms: 340 mg IMVT-1401 weekly (N=5), 680 mg IMVT-1401 weekly (N=5), and placebo (N=5). Initially, the trial had a target enrollment of 21 patients, however, after taking into consideration the impact of COVID-19 as well as recent data from other anti-FcRn programs that have validated this mechanism in MG, Immunovant elected to unblind and report the study with 15 patients enrolled.

As evaluated in a pre-specified, pooled analysis of 15 patients who completed Day 42, IMVT-1401-treated patients (N =10) showed a mean3.8-point improvement on the MG Activities of Daily Living ("MG-ADL") scale vs. a mean decline of +0.6 for placebo, a result that was statistically significant (p = 0.029). IMVT-1401-treated patients also showed a highly statistically significant improvement on the MG Composite ("MGC") scale, with an average improvement of 8.0 points vs. a mean decline of +1.4 for placebo (p = 0.006).

MG-ADL responder rates, defined as the percentage of patients showing a \geq 2-point improvement, were 60% for IMVT-1401-treated patients vs. 20% for placebo. MG-ADL deep responder rates, defined in the study as the percentage of patients showing a \geq 6-point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo. MGC deep responder rates, defined in the study as the percentage of patients showing a \geq 10-point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo.

Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be well-tolerated with no serious adverse events reported, no withdrawals due to adverse events, and no imbalance in headaches. Mean reductions in total serum IgG from baseline to Day 42 for the 340 mg and 680 mg cohorts were 59% and 76%, respectively.

In addition, Immunovant has updated its anticipated clinical development timelines. Immunovant anticipates initiating its Phase 3 clinical trial of IMVT-1401 in patients with MG in the first half of calendar year 2021. Immunovant currently remains on track to report initial results from its ASCEND GO-2 trial, a Phase 2b clinical trial of IMVT-1401 for thyroid eye disease in the United States, Canada and Europe, in the first half of calendar year 2021. Immunovant plans to report initial results from the high-dose cohort of its Phase 2a trial of IMVT-1401 in patients with warm autoimmune hemolytic anemia in the first quarter of calendar year 2021. Immunovant intends to announce three new indications over the next 12 months.

This Current Report on Form 8-K contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Immunovant makes regarding the timing, progress and reporting of results of its clinical programs and the timing of the announcement of future indications are forward-looking. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others, initial results or other preliminary analyses or results of early clinical trials may not be predictive of final trial results or of the results of later clinical trials; future clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this Current Report on Form 8-K; any product candidates that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant's product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic on Immunovant's clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, IMVT-1401; and Immunovant will require additional capital to fund its operations and advance IMVT-1401 through clinical development. These and other risks and uncertainties are more fully described in Immunovant's periodic and other reports filed with the SEC, including in the section titled "Risk Factors" in Immunovant's most recent Quarterly Report on Form 10-Q filed with the SEC on August 12, 2020, and Immunovant's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated August 25, 2020.
99.2	Presentation dated August 25, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 25, 2020

IMMUNOVANT, INC.

By: /s/ Peter Salzmann, M.D.

Peter Salzmann, M.D. Chief Executive Officer

Immunovant Announces Positive Topline Results from Multi-Center, Placebo-Controlled Phase 2a Trial of IMVT-1401, A Novel Investigational Anti-FcRn Antibody Delivered by Subcutaneous Injection, in Myasthenia Gravis

Company to Host Conference Call on August 25, 2020 at 8:30am EDT

- 3.8-point mean improvement on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale was statistically significant vs. placebo (p = 0.029)
- 8.0-point mean improvement on Myasthenia Gravis Composite (MGC) scale was highly statistically significant vs. placebo (p = 0.006)
- Mean reductions in total IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively
- IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs) and no withdrawals due to adverse events (AEs)
- Registration-enabling Phase 3 MG trial is expected to initiate in the first half of 2021

NEW YORK, August 25, 2020 (GLOBE NEWSWIRE) – Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases, today announced positive topline results from ASCEND MG, a Phase 2a study of IMVT-1401 in patients with myasthenia gravis (MG).

The multi-center, randomized, placebo-controlled trial was designed to evaluate the safety, tolerability, pharmacodynamics, and efficacy of IMVT-1401 in patients with moderate-to-severe generalized MG. Results from the six-week treatment period included three arms: 340 mg IMVT-1401 weekly (N=5), 680 mg IMVT-1401 weekly (N=5), and placebo (N=5).

As evaluated in a pre-specified, pooled analysis of 15 patients who completed Day 42, IMVT-1401-treated patients (N=10) showed a mean 3.8-point improvement on the MG-ADL scale vs. a mean decline of +0.6 for placebo, a result that was statistically significant (p = 0.029). IMVT-1401-treated patients also showed a highly statistically significant improvement on the MGC scale, with an average improvement of 8.0 points vs. a mean decline of +1.4 for placebo (p = 0.006).

MG-ADL responder rates, defined as the percentage of patients showing $a \ge 2$ -point improvement, were 60% for IMVT-1401-treated patients vs. 20% for placebo. MG-ADL deep responder rates, defined in the study as the percentage of patients showing $a \ge 6$ -point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo. MGC deep responder rates, defined in the study as the percentage of patients showing $a \ge 10$ -point improvement, were 40% for IMVT-1401-treated patients vs. 0% for placebo.

Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no imbalance in headaches. Mean reductions in total serum IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively.

"We are absolutely thrilled with the results of this trial," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "The clinical benefits we observed in this trial provide strong support that IMVT-1401 might ultimately become a best-in-class anti-FcRn agent for MG patients. Importantly, IMVT-1401

was delivered by subcutaneous injection, opening the future possibility of at-home, self-administered treatment rather than infusion center-based treatment. We look forward to engaging with the FDA later this year on the design of our Phase 3 registrational program in MG."

After taking into consideration the impact of COVID-19 and the validation of the anti-FcRn mechanism in MG as discussed in its June 29th press release, Immunovant elected to unblind the study after 15 of an anticipated 21 patients had completed the six-week treatment course.

"Although this small Phase 2a study was designed principally to evaluate safety and tolerability, as well as changes in IgG antibodylevels, it is extremely encouraging to see such promising early results on a range of MG outcome measures," said Michael Benatar, M.D., M.S., Ph.D., Chief of the Neuromuscular Division at the University of Miami. "Results of this study will provide critical insights for the design and implementation of a pivotal phase 3 study," he added.

Immunovant will host a conference call on Tuesday, August 25 at 8:30am EDT. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast, please visit Immunovant's website a<u>twww.immunovant.com</u>. Participants may also dial in using the numbers provided below:

Toll Free: 1-877-407-9039 **Toll/International:** 1-201-689-8470

An archived webcast recording will be available on the Immunovant's website for a limited time.

About Immunovant, Inc.

Immunovant, Inc is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. Immunovant is developing IMVT-1401, a novel, fully human anti-FcRn monoclonal antibody, as a subcutaneous injection for the treatment of autoimmune diseases mediated by pathogenic IgG antibodies.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "wull," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Immunovant makes regarding Immunovant's progress towards its vision of enabling normal lives for patients with autoimmune diseases; the potential of IMVT-1401 to become a best-in-class treatment option for patients suffering from MG; and the design and implementation of a pivotal Phase 3 study of IMVT-1401 for the treatment of MG are forward-looking. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others: initial results or ofher preliminary analyses or results of early clinical trials may not be predictive of final trial results or of the results of later clinical trials; future clinical trials may not progress through clinical development or receive required regulatory approvals within expected timelines or at

all; Immunovant's product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic on Immunovant's clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, IMVT-1401; and Immunovant will require additional capital to fund its operations and advance IMVT-1401 through clinical development. These and other risks and uncertainties are more fully described in Immunovant's most recent Quarterly Report Form 10-Q filed with the SEC on August 12, 2020, and Immunovant's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact:

John Strumbos, PhD, MBA Vice President, Finance and Strategy Immunovant, Inc. info@immunovant.com



ASCEND MG Topline Results Conference Call

August 25, 2020

Forward-looking statements

This presentation contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "future," "potential," "continue" and other similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. For example, forward-looking statements include statements Immunovant makes regarding its business strategy, its plans to develop and commercialize its product candidates, the potential safety and efficacy of Immunovant's current or future product candidates, its expectations regarding timing, the design and results of clinical trials of its product candidates, Immunovant's plans and expected timing with respect to regulatory filings and approvals, the size and growth potential of the markets for Immunovant's product candidates, and its ability to serve those markets. All forward-looking statements are based on estimates and assumptions by Immunovant's management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others: initial results or other preliminary analyses or results of early clinical trials may not be predictive final trial results or of the results of later clinical trials; future clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this presentation; any product candidates that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant's product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic on Immunovant's clinical development plans and timelines; Immunovant's business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, IMVT-1401; Immunovant is at an early stage in development of IMVT-1401; and Immunovant will require additional capital to fund its operations and advance IMVT-1401 through clinical development. These and other risks and uncertainties are more fully described in Immunovant's periodic and other reports filed with the Securities and Exchange Commission (SEC), including in the section titled "Risk Factors" in Immunovant's most recent Quarterly Report on Form 10-Q filed with the SEC on August 12, 2020. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.



ASCEND MG topline results are extremely encouraging for patients suffering from Myasthenia Gravis

Only subcutaneous injection anti-FcRn agent in clinical development for MG

Safety and tolerability findings similar to prior IMVT-1401 studies



Robust, dose-dependent, IgG reductions

Statistically significant improvements in MG-ADL and MGC scales

High rate of deep responders across MG scales

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Myasthenia Gravis overview

- Rare autoimmune disorder affecting an estimated 66,000 people in the US¹
- Characterized by weakness of voluntary muscles including ocular, facial, oropharyngeal, limb, and respiratory muscles¹
- 15-20% of MG patients will experience at least one myasthenic crisis over their lifetimes, a potentially life-threatening acute complication²
- Disease caused by autoantibodies targeting the neuromuscular junction¹
- ~93% of patients have an identified autoantibody¹

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- Anti-acetylcholine receptor (AChR) antibodies (~85%)
- Anti-muscle-specific tyrosine kinase (MuSK) antibodies (~8%)



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Meriggioli M.N. and Sanders D.B. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert

- Meriggioli M.N. and Sanders D.B. N Review Clinical Immunology, 2012
- Sudulagunta S.R., et al. Refractory myasthenia gravis clinical profile, comorbidities and response to rituximab. German Medical Science, 2016

ASCEND MG: Phase 2a study design



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Note: Initial target enrollment was 21 patients, however trial was unblinded after 15 patients had completed treatment phase.

ASCEND MG: Patient baseline characteristics



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	Placebo (N=5)	IMVT-1401 (N=10)
Age, Mean <u>+</u> SD	39 <u>+</u> 17	64 <u>+</u> 20
Gender, % Male / % Female	20% / 80%	70% / 30%
MGFA Disease Class at Screening, N (%) II III IVa	2 (40%) 3 (60%) 0 (0%)	3 (30%) 6 (60%) 1 (10%)
Baseline QMG Score, Mean <u>+</u> SD	18.0 <u>+</u> 2.7	16.4 <u>+</u> 2.8
Baseline MG-ADL Score, Mean <u>+</u> SD	8.0 <u>+</u> 3.9	8.5 <u>+</u> 3.4
Baseline MGC Score, Mean <u>+</u> SD	17.2 <u>+</u> 6.1	17.3 <u>+</u> 4.6
Prior / Concomitant Treatments, N (%) Acetylcholinesterase inhibitors Corticosteroids Immunosuppressants	4 (80%) 4 (80%) 2 (40%)	8 (80%) 9 (90%) 5 (50%)

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Safety and tolerability findings similar to prior Phase 1 and 2 data



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ASCEND MG topline results

	Placebo (N=5)	IMVT-1401 (N=10)
TEAEs reported by ≥ 2 participants (all arms) Injection site erythema Muscle spasms Injection site swelling Headache Dizziness	1 2 1 1 0	2 1 1 1 2
Severe (Grade 3+) TEAEs	0	0
TEAEs resulting in withdrawal	0	0
SAEs	0	0
Mean albumin reduction from baseline to Day 42	-4%	-16% (340 mg) -26% (680 mg)



Note: All albumin reductions were asymptomatic. **TEAE:** Treatment-emergent adverse event. **SAE:** Serious adverse event.

Robust, dose-dependent, IgG reductions



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ASCEND MG topline results



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Note: Red arrows indicate weekly doses of IMVT-1401 at 340 mg or 680 mg. Error bars represent standard deviation of the mean.

Statistically significant and clinically meaningful improvements in MG-ADL



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ASCEND MG topline results



IMVT-1401 group represents pooled data from 10 patients receiving either 340 mg or 680 mg IMVT-1401 weekly. * Indicates ANCOVA p = 0.029. Error bars represent standard error of the mean.
 MG-ADL responders defined as patients showing ≥ 2-point improvement.

Overview of clinical efficacy measures utilized as endpoints in ASCEND MG



Myasthenia Gravis Activities of Daily Living (MG-ADL):

- Patient-reported questionnaire
- Comprised of 8 items reflecting ocular, bulbar, respiratory, and limb symptoms and their impact on function
- Validated FDA regulatory endpoint

Quantitative Myasthenia Gravis (QMG):

- Physician assessment
- Comprised of 13 items reflecting ocular symptoms, facial/oropharyngeal symptoms, and nonfacial symptoms
- · Lung function test challenging to administer during pandemic

Myasthenia Gravis Composite (MGC):

- · Combination patient and physician assessment
- 10 test items selected using the following criteria:
 - · Meaningful to both the physician and the patient
 - · Frequently abnormal in patients with active disease
 - Responsive to clinical change
- Currently endorsed by the Myasthenia Gravis Foundation of America (MGFA) as the scale of choice for prospective studies in MG

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Statistically significant and clinically meaningful improvements in MG scales







Note: IMVT-1401 group represents pooled data from 10 patients receiving either 340 mg or 680 mg IMVT-1401 weekly. * Indicates ANCOVA p = 0.029. ** Indicates ANCOVA p = 0.006. ANCOVA for QMG p = 0.068

High rate of deep responders¹ across MG scales



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ASCEND MG topline results



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 MG-ADL and QMG deep responder threshold was ≥ 6-point improvement from baseline, MGC threshold was ≥ 10-point improvement from baseline. IMVT-1401 group represents pooled data from 10 patients receiving either 340 mg or 680 mg IMVT-1401 weekly.

ASCEND MG topline results are extremely encouraging for patients suffering from Myasthenia Gravis

Only subcutaneous anti-FcRn agent in clinical development for Myasthenia Gravis

Positive clinical results after 6 weeks of treatment	Observed to be safe and generally well-tolerated
 3.8-point mean improvement on MG-ADL (p = 0.029) 8.0-point mean improvement on MGC (p = 0.006) 40% deep responder rate on the MG-ADL* vs 0% for placebo 40% deep responder rate on the MGC** vs 0% for placebo 	 Subcutaneous injection No serious adverse events (SAEs) were reported No withdrawals due to adverse events (AEs) All reported AEs were mild or moderate
MG-ADL: Myasthenia Gravis Activit	ties of Daily Living; MGC: Myasthenia Gravis Composite

*MG-ADL: Myasthenia Gravis Activities of Daily Living; MGC: Myasthenia Gravis Composi *MG-ADL deep responders defined as patients showing a \geq 6-point improvement **MGC deep responders defined as patients showing a \geq 10-point improvement 13

IMVT-1401: A pipeline in a product

Target Indication	2H20	1H21	2H21	Anticipated Milestones
Myasthenia Gravis (MG)		MG Phas	se 3	Phase 3 initiation expected in 1H21
Thyroid Eye Disease (TED)	ASCEND GO-2			Phase 2b results expected in 1H21
Warm Autoimmune Hemolytic Anemia (WAIHA)	ASCEND WAIHA			Phase 2a Cohort 1 results expected in 1Q21
Indication #4	Indicatio	on #4		Three new indications expected to be
Indication #5	Indication #5			announced over next 12 months
Indication #6	Indicatio	on #6		

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Question and answer session