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September 8, 2020
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Heat Biologics Inc (HTBX - NASDAQ)

Breaking into the Big Leagues: $100 Million + 3 Clinical Candidates

Based on our DCF model and a 15% discount rate, Heat Biologics is valued at approximately $3.50 per share. Our model applies a 15% probability of ultimate approval and commercialization for HS-110 in a broad NSCLC setting. The model includes contributions from the US, EU and rest of world.

Current Price (9/4/2020)	$1.02
Valuation	**$3.50**

OUTLOOK

Heat Biologics has two novel immunotherapies in clinical development designated ImPACT & ComPACT. The candidates use genetically-modified cells to secrete a broad array of cancer antigens accompanied by a gp96 adjuvant to stimulate a CD8+ T cell mediated anti-cancer immune response. In response to COVID-19, Heat has launched a vaccine program using the gp96 platform.

The company's lead indication in NSCLC is addressed with portfolio candidates HS-110 and HS-130, both administered in conjunction with checkpoint inhibitors. Heat is currently conducting Phase II trials for HS-110 and begun dosing HS-130 patients in a Phase I study. Other pipeline constituents emerged from the company's acquisition of Pelican Therapeutics in 2017. Pelican is developing a T-cell co-stimulating antibody targeting the cell surface receptor TNFRSF25 called PTX-35 which began Phase I trial in June 2020.

The valuation assumes a 2023 FDA approval of HS-110 and a 2024 launch of the compound in the US, followed by a 2025 launch in the EU and rest of world that will be achieved through the efforts of partners. HS-130 and PTX-35 are anticipated to be launched in 2028 in the US and 2029 in other regions.

SUMMARY DATA

52-Week High	**4.30**
52-Week Low	**0.20**
One-Year Return (%)	**88.9**
Beta	**0.43**
Average Daily Volume (sh)	**31,129,396**
Shares Outstanding (mil)	**148.6**
Market Capitalization ($mil)	**151.5**
Short Interest Ratio (days)	**0.1**
Institutional Ownership (%)	**13.6**
Insider Ownership (%)	**6.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.7 A	$0.3 A	$0.0 A	$2.0 A	$3.0 A
2020	$0.9 A	$0.6 A	$0.6 E	$0.6 E	$2.8 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.17 A	-$0.14 A	-$0.18 A	-$0.10 A	-$0.60 A
2020	-$0.11 A	-$0.05 A	-$0.04 E	-$0.05 E	-$0.22 E
2021					-$0.19 E
2022					-$0.20 E

WHAT'S NEW

Second Quarter 2020 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported second quarter 2020 results in an August 7th release concurrent with the submission of the 10-Q to the SEC. Heat has been busy advancing preclinical work for a coronavirus vaccine, assembling data related to the Phase II HS-110 DURGA trial and raising significant capital to support the pipeline of projects. Heat management has also attended scientific and investor events sharing the company's development progress. The company is in the process of preparing a data package to share with the FDA in an End-of-Phase II meeting that we expect will be scheduled soon. Phase I trials for PTX-35 and HS-130 for solid tumors are now underway and we add a valuation component for these candidates for the first time. The company also announced the issuance of patent 10,758,611 for a vector co-expressing vaccine and costimulatory molecules.

Revenues for the second quarter were $0.6 million, representing the recognition of grant income from CPRIT supporting the PTX-35 T cell activation platform. Research and development expenditures totaled $2.8 million, down 18% compared with the prior year second quarter amounts, as patients transitioned from active treatment to long-term follow up and as a result of lower manufacturing costs related to PTX-35. These declines were offset by a slight increase in HS-130 costs related to regulatory consulting and investigator site payments and the initiation of coronavirus programs. General and administrative expenses fell 3% to $1.8 million. Other expenses totaled $0.2 million and interest earned from cash and equivalents was $56,000. Net loss for 2Q:20 was ($4.5) million or ($0.05) per share compared with ($4.8) million or ($0.14) per share in 2Q:19.

Cash and equivalents as of June 30, 2020 were $47.0 million, compared to $14.8 million at the end of 2019. Heat continues with no debt on the books. Cash burn was ($4.5) million in the first quarter compared with ($4.1) million in 2Q:19. Net cash provided by financing activities totaled $24.5 million, representing proceeds from the issuance of common stock. Following the end of the reporting period, Heat raised an additional $58.5 million in capital from its at-the-market (ATM) facility and reported over $100 million in cash and short term investments as of August 6, 2020.

Coronavirus

The global threat of coronavirus has changed the landscape for many biotechnology research and development companies. The spread of the virus may delay trial progression and the availability of drug product. But, it also has accelerated programs that many companies, including Heat Biologics, have developed in infectious disease. Heat's wholly-owned subsidiary, Zolovax, has been focused on developing medicines and vaccines for infectious diseases using the glycoprotein platform, gp96, for many years. Previous research has been conducted for simian immunodeficiency virus, malaria and Zika. In March 2020, Heat entered into a research agreement with the University of Miami (UM) to sponsor new research and development of a SARS-CoV-2 (COVID-19) vaccine and diagnostic test.

The vaccine incorporates multiple SARS-CoV-2 antigens using the gp96 platform. The approach is expected to induce long-term immunity and provide protection against future infections. As no viral vector is used, Heat's coronavirus vaccine avoids anti-vector immunity and viral activation while activating T and B cells with high immunogenicity. The activation of T and B cells drives induction of mucosal immunity and long-term memory response. In early March, the company filed multiple provisional patent applications for its technology that treat and prevent infection from the SARS-CoV-2 virus. Heat's approach may also be appropriate in combination with other vaccines that activate the humoral immune system on account of its complementary stimulation of the adaptive immune system.

Since our last report, Heat has provided updates to its progress for the coronavirus programs, achieving stable expression of gp96/nCoV-S protein and identifying a manufacturing partner in Waisman Biomanufacturing.

Heat has identified several milestones for the COVID-19 vaccine program in second quarter 2020. These include the completion of a cell-based vaccine containing gp96-Ig; OX40L-Ig; and SARS-CoV-2 protein S, development of proof-of-concept; animal-model data demonstrating vaccine immunogenicity and continued sourcing of funding to support the development efforts. In late July, Heat confirmed successful pre-clinical testing of the vaccine,

confirming immunogenicity in animal models. The vaccine was shown to expand human-HLA[1]-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein.

After the second quarter report, Heat provided an update on the coronavirus program providing additional preclinical data for Heat's gp96-based vaccine. In an animal model, the COVID-19 vaccine stimulated expansion of both killer CD8+ T cells and helper CD4+ T cells. These immune cells destroy virally infected cells and assist in producing antibodies specific to the virus. Both the CD8+ and CD4+ cells release cytokines that augment the immune response and migrate to the lungs and airways where the SARS-CoV-2 infection resides. Heat was involved in two COVID-19 publications in the last months including a white paper on "The Importance of T-Cell Immunity in SARS-CoV-2 Infection" and the preclinical COVID-19 vaccine results in a paper entitled "Induction of SARS-CoV-2 protein S-specific CD8+ T cells in the lungs of gp96-Ig-S vaccinated mice."

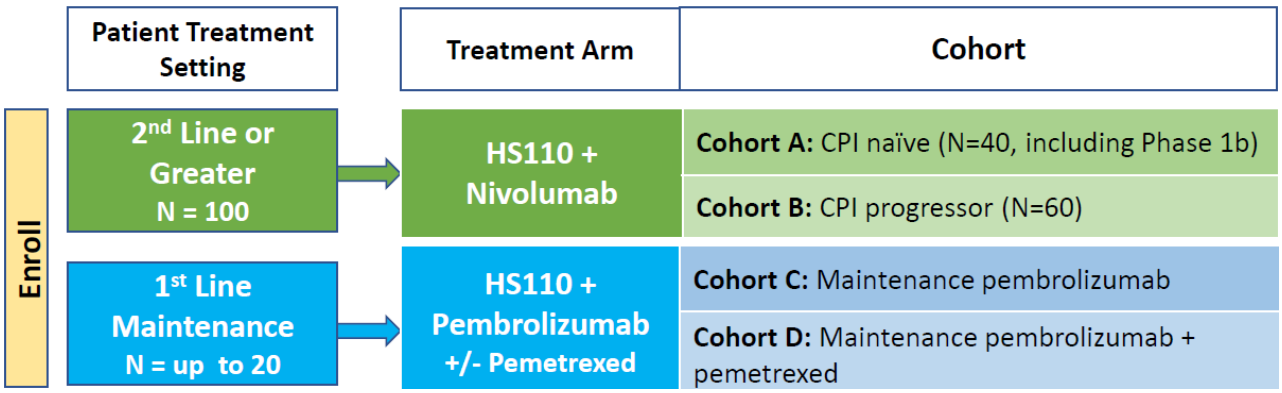
The white paper concluded that protective antibody responses alone may be insufficient to successfully clear SARS-CoV-2. T-cell responses, which are critical for priming antibody-producing B cells, will likely be required for a long-term response against the virus. Some cited studies have shown that patients with higher antibody titers were associated with stronger CD4 T cell responses. In other viral studies, patients maintain long-lasting memory T cells, while antibody responses dissipate. Heat's gp96/OX40L vaccine coordinates humoral and cellular immune response and may be an efficient approach to stimulating an effective attack against SARS-CoV-2. Heat's vaccine stimulates a cellular immune response through CD4+ and CD8+ T cells and a humoral immune response with the neutralizing IgG antibody. Gp96 alerts the immune system that a strong immune response is necessary and OX40L expands CD4 helper T cells that promote B cell differentiation and IgG/IgA antibody class switching. The paper further detailed Heat's use of its gp96 platform to deliver antigens representing the SARS-CoV-2 spike protein to induce cell-mediated immune responses. The *in vivo* work confirmed that the approach generates a spike specific CD4+ and CD8+ response in the respiratory system.

Heat has made the case for using its approach, if ultimately approved, along with other vaccines to improve protection against COVID-19. Many other vaccines that are being developed for the virus stimulate an antibody response and if used in conjunction with Heat's gp96 approach, the combination would add T cell immunity for more durable protection.

HS-110

The HS-110 Phase II Durga trial provided the latest update to its interim data in mid-November 2019. Cohort A enrolled checkpoint-inhibitor naïve patients and Cohort B enrolled patients previously on checkpoint inhibitor therapy that have progressed. Both groups are treated with a combination of HS-110 and nivolumab. Initial results have been promising. There are two additional cohorts, designated C and D that will examine HS-110 in combination with pembrolizumab, and pembrolizumab and chemotherapy which are intended to evaluate safety with an alternative checkpoint inhibitor. About 20 patients are expected to be enrolled in the C and D cohorts with 122 patients enrolled overall.

Exhibit I – HS-110 Trial Design[2]

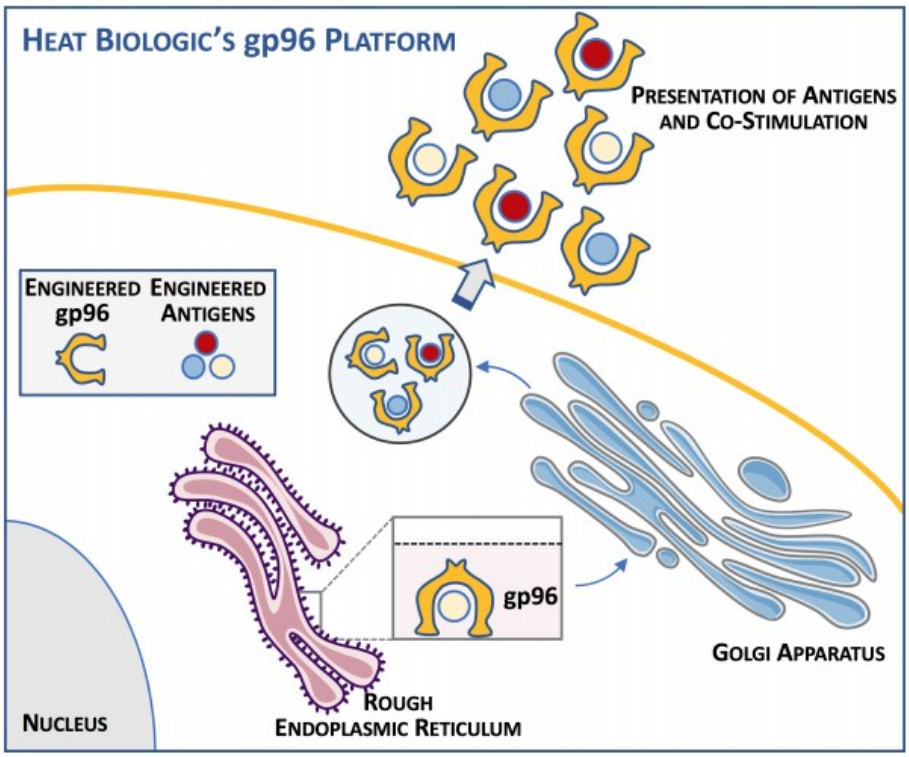


[1] HLA: Human Leukocyte Antigen
[2] Source: Heat Biologics Corporate Presentation. November 5, 2019.

ASCO 2020 Abstract

Heat participated in the 2020 American Society of Clinical Oncology (ASCO) meeting presenting the company's poster entitled: "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab." The abstract highlights Cohort A in the Durga trial that combines HS-110 with nivolumab in the 47-patient study. Subjects enrolled in this group exhibited an overall survival duration of 28.7 months. The cohort was divided into patients based on whether their tumor-antigens were similar to those in HS-110. (≥8 vs <8 antigens in common). Patients whose cancer testis antigen (CTA) had higher similarity to HS-110 experienced a longer median overall survial.

Exhibit II – gp96 Platform[3]



PTX-35

In early June, Heat announced that the FDA had cleared its investigational new drug application (IND) for PTX-35 followed shortly after by the initiation of the first clinical site for the trial and the appointment of Anthony Tolcher, MD as lead investigator. By the end of June, the first patient had been treated in the Phase I trial to evaluate PTX-35. Up to 30 patients are expected to be enrolled

As a reminder, PTX-35 is being developed by 85% owned subsidiary, Pelican Therapeutics, and we allocate royalties accordingly. There is also a relatively complex royalty arrangement with Cancer Prevention and Research Institute of Texas (CPRIT) that includes a return of 4x the original grant and a 0.5% royalty in perpetuity. There are a number of milestones owed to Pelican by Heat that we also reflect in our new valuation.

HS-130

In an August 12, 2019 release, Heat announced that its IND for HS-130 had been submitted and received clearance from the FDA to begin a Phase I safety trial. On December 16, the first patient was dosed in the dose escalation trial. The combination study, which will pair HS-130 with HS-110, will enroll patients with advanced solid tumors refractory to standard of care. The candidate is in development to treat solid tumors and will employ ComPACT technology that delivers gp96 heat shock protein along with a T-cell co-stimulatory fusion protein (OX40L). The associated trial expects to enroll up to 30 patients and have primary endpoints of safety and optimal dose determination for its Phase II trial.

[3] Source: Heat Biologics Corporate Presentation. May 2020.

The Phase I trial of HS-130 suffered an enrollment pause during the months of April and May this year due to lack of personal protective equipment at a clinical site. When the equipment became available, enrollment resumed and no further delays in development milestones are expected for HS-130.

Patent Issued

On September 2nd, 2020, the issuance of a key patent was announced entitled Vector co-expressing vaccine and costimulatory molecules. The composition of matter patent addresses methods of co-expressing a secretable vaccine protein, such as gp96, and T cell co-stimulatory molecules from a single vector. The patent was filed in June 2018 and issued on September 1st, 2020. Heat is conducting preclinical studies using both gp96 and the OX40L T cell co-stimulator in a single therapy advancing the work represented in the intellectual property, which can be used not only in oncology but also in infectious disease such as COVID-19. Anticipated advantages of the work represented here include enhanced memory T cell response, limited systemic toxicity and cost advantages compared to other systemic therapies.

Corporate Milestones

Below we list key milestones for Heat Biologics.

- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- HS-130 (ComPACT) IND filing and FDA Clearance – August 2019
- HS-110 interim data readout – November 2019
- HS-110 Phase II interim readout – 4Q:19
- First patient dosed in HS-130 Phase I – December 2019
- PTX-35 IND clearance and first patient dosing – 2Q:20
- ASCO Poster Presentation – May 29, 2020
- Various coronavirus vaccine milestones – 2020
- Discussion with potential partners – Ongoing
- Complete HS-130 Phase I trial – 4Q:20
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2020

Pipeline

Exhibit III – Heat Biologics Product Pipeline[4]

Product	MOA (Modality)	Indication	Preclinical	Phase 1	Phase 2	Phase 3
HS-110	gp96 + CTAs (Cell Therapy)	NSCLC				
HS-130	OX40L (Cell Therapy)	Solid Tumors				
COVID-19 Vaccine	gp96 + Viral Antigens (Cell Therapy)	COVID-19				
PTX-35	TNFRSF25 (mAb)	Solid Tumors				

[4] Source: Heat Biologics August 2020 Corporate Presentation.

Sources of Capital

Heat Biologics started 2020 with $15 million in cash on the balance sheet and during the first six months of the year raised $6.6 million from a public offering of common stock and warrants and $37.0 million from the issuance of common stock which left the company with a cash balance of $47 million as of June 30, 2020. Following the end of the quarter, Heat issued an additional 36.1 million shares raising an additional $58.5 million bringing the total cash balance to over $100 million as of early August 2020.

Valuation

Since our last report, Heat Biologics has advanced two new candidates into the clinic and increased its cash on hand to $100 million. This substantial transformation will both increase the value of the company and divide it among a greater number of shares. Assumptions for HS-110 will continue as before and include approval in 2023 followed by commercialization in the US in 2024 and rest of world, including Europe, in 2025. The addressable market in NSCLC is estimated to be 186,000 in the US, 250,000 in the European Union and 980,000 in the rest of the world. Initial penetration into the NSCLC market is estimated to be 2.5%, increasing to 8% by year four. Our pricing forecasts recognize that HS-110 and Heat's other candidates are intended to be used in combination with checkpoint inhibitors. Combining multiple immunology drugs rapidly escalates treatment cost which will likely get pushback from payors and patients; therefore we forecast an $83,000 per treatment price point in 2024 for HS-110 in the US. This is below the $100,000+ price range that immunotherapies have commanded in the US market. We apply the same per treatment cost to HS-130 and PTX-35 in the United States. For the EU, we apply a 50% discount and assume a $42,000 price point and for rest of world we apply a 70% discount and assume a $25,000 cost per course of treatment. Therapy cost inflation is forecast to be 2% per year.

Our new forecasts assume that HS-130 traverses phased clinical trials and an NDA submission over the 2020 to 2027 period. Assuming approval, commercialization will begin in 2028 in the US and 2029 in both the EU and rest of world. Pricing will match HS-110 levels in each of the regions and with inflation will be approximately $90,000 in the US, $45,000 in the EU and $27,000[5] in the rest of the world for both compounds. We continue to assume that royalty revenues will be a net 25% paid to Heat for HS-110 and HS-130. Cash development costs, which include both R&D and G&A, will run about $26 million in 2020, rise to $35 million by 2026, decline to $28 million in 2027, then hold steady at $2 million per year for 2028 and beyond as the company retires to collect royalties. It is likely that either Heat will be acquired or it will develop new products. When additional candidates are added we will include the anticipated benefits and costs.

PTX-35 has additional considerations to reflect obligations to CPRIT and the 85% ownership of the entity by Heat. The reimbursement of funds to CPRIT is complex and includes repayment of 400% of the original investment through a sliding royalty scale and a 0.5% royalty in perpetuity. There are also a series of milestones that will be paid to Pelican shareholders that we estimate in the model. We simplify the approach and assume 1.5% of PTX-35 product revenues are repaid to CPRIT over the duration of the forecast. We also estimate 85% of the remaining royalty to be paid to Heat.

Cash taxes are estimated at 25% of profits and will be recognized after estimated accumulated net operating losses are exhausted. We continue to use a 15% discount rate in our discounted cash flow model and assume a 15% probability of success for each of the candidates. Based on our updated shares outstanding of 162 million, which includes restricted shares, exercised warrants and options we generate a target price of $3.50 per share.

Summary

Heat Biologics has made substantial progress this year with the entry of HS-130 and PTX-35 into the clinic. Substantial preclinical work has also taken place for a coronavirus vaccine which may enter the clinic next year. Year to date, Heat has been opportunistic in raising capital and has accumulated over $100 million on the balance sheet that should sustain operations for the next several years.

We update our valuation to reflect the increase of shares outstanding and the entry of HS-130 and PTX-35 into the clinic. Our valuation work generates a target price of $3.50.

[5] The higher initial price vs. HS-110 reflects the 2% annual inflation rate in therapy cost.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$3.0**	**$0.9**	**$0.6**	**$0.6**	**$0.6**	**$2.8**	**$0.0**	**$0.0**
YOY Growth								
Research & Development	$13.0	$2.8	$2.8	$5.2	$6.2	$17.0	$19.5	$20.1
General & Administrative	$9.4	$3.3	$1.8	$2.2	$2.4	$9.7	$10.0	$11.2
Other	$1.4	($0.0)	$0.8	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($20.7)	($5.1)	($4.8)	($6.8)	($8.0)	($23.8)	($29.5)	($32.3)
Interest Income	$0.4	$0.1	$0.1	$0.1	$0.1	$0.3	$0.0	$0.0
Other Income	($0.0)	($1.3)	$0.2	$0.0	$0.0	($1.1)	$0.0	$0.0
Pre-Tax Income	($20.3)	($6.4)	($4.5)	($6.7)	($7.9)	($24.6)	($29.5)	($32.3)
Provision for Income Tax	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*
Net Income	**($20.4)**	**($6.4)**	**($4.5)**	**($6.7)**	**($7.9)**	**($24.6)**	**($29.5)**	**($31.3)**
Non-controlling Interest	($0.4)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.8)	
Net Income After NCI	**($20.0)**	**($6.3)**	**($4.5)**	**($6.6)**	**($7.8)**	**($24.2)**	**($28.7)**	**($31.3)**
Net Margin	*-669%*	*-707%*	*-765%*	*-1117%*	*-1317%*	*-878%*	*-*	*# DIV/0!*
Reported EPS	**($0.60)**	**($0.11)**	**($0.05)**	**($0.04)**	**($0.05)**	**($0.22)**	**($0.19)**	**($0.20)**
YOY Growth	*-33%*	*-35.6%*	*-64.7%*	*-75.8%*	*-48.2%*	*-64%*	*-15%*	*6%*
Basic Shares Outstanding	33.28	57.28	87.93	148.00	150.00	110.80	155.00	160.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart

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