# Zacks Small-Cap Research

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## Phio Pharmaceuticals Corp (PHIO - NASDAQ)

***Two Compounds Entering Clinic in 2020***

Based on our DCF model and a 15% discount rate, Phio Pharmaceuticals is valued at approximately $2.00 per share. Our model applies a 15% probability of ultimate approval and commercialization for RXI-109 and Samcyprone. The model includes contributions from the US, EU and rest of world.

| | |
|---|---|
| Current Price (6/7/2019) | $0.40 |
| **Valuation** | **$2.00** |

### OUTLOOK

Phio Pharmaceuticals has developed a unique composition of interference RNA that is able to self-deliver into the cellular cytoplasm. The compound, sd-rxRNA, combines features of RNAi and antisense, and is able to silence unwanted gene expression with a limited side effect profile.

The company has two Phase II dermal assets and one Phase I/II ocular asset which are expected to be partnered and provide development capital for earlier stage immuno-oncology (IO) programs.

Phio recently directed its primary research focus towards its preclinical IO program that is being developed to augment existing cell therapies. A favorable investment and regulatory environment are supportive of IO and should allow for rapid entry into the clinic.

We attach a valuation to the Phase I/II and Phase II assets and expect to see regulatory approvals and subsequent commercialization over the 2022 to 2024 period as described in our analysis.

### SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **2.52** |
| **52-Week Low** | **0.27** |
| **One-Year Return (%)** | **-83.9** |
| **Beta** | **2.07** |
| **Average Daily Volume (sh)** | **743,353** |
| **Shares Outstanding (mil)** | **23.9** |
| **Market Capitalization ($mil)** | **9.6** |
| **Short Interest Ratio (days)** | **3.23** |
| **Institutional Ownership (%)** | **13.8** |
| **Insider Ownership (%)** | **5.9** |
| **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 2018 Estimate** | **N/A** |
| **P/E using 2019 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) |
|---|---|---|---|---|---|
| 2018 | $0.0 A | $0.1 A | $0.1 A | $0.0 A | $0.1 A |
| 2019 | $0.0 A | $0.0 E | $0.0 E | $0.0 E | $0.0 E |
| 2020 | | | | | $0.0 E |
| 2021 | | | | | $0.0 E |

**Earnings per Share**

| | Q1 | Q2 | Q3 | Q4 | Year |
|---|---|---|---|---|---|
| 2018 | -$0.90 A | -$0.46 A | -$0.34 A | -$0.09 A | -$1.80 A |
| 2019 | -$0.10 A | -$0.08 E | -$0.08 E | -$0.09 E | -$0.36 E |
| 2020 | | | | | -$0.35 E |
| 2021 | | | | | -$0.25 E |


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## WHAT'S NEW

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) reported first quarter 2019 results and filed its Form 10-Q on May 14, 2019. Since the beginning of the year, the company has announced a new collaborations with Glycostem Therapeutics, the promotion of Dr. Gerrit Dispersyn to CEO and the appointment of Dr. John Barrett as CDO. Phio is focusing its efforts on two assets in two indications designated PH-762 and PH-804 for melanoma and other cancers using checkpoint inhibition in adoptive cell transfer and modifying the tumor micoenvironment.

Phio's lead candidate, PH-762,[1] is pursuing immuno-oncology indications in collaboration with Center for Cancer Immune Therapy (CCIT) and Iovance Biotherapeutics. Development efforts are centered on reducing the immune checkpoints that appear on the surface of tumor infiltrating lymphocytes (TILs) in an approach that can be layered on to current manufacturing processes. *In-vitro* efficacy and safety data is being generated and regulatory work is underway in order to prepare the investigational new drug (IND) application. Phio is currently developing the data set needed to satisfy the requirements for the IND and we expect a further update on progress in a few months.

Revenues of $21,000 were recognized in the quarter and reflect the work performed in the collaboration with BioAxone to treat spinal cord injury. 1Q:19 expenditures fell 4% to $2.2 million as research and development expenditures declines and general and administrative expenses increased. R&D contracted due to headcount reductions, lower payroll expenses and completion of PH-762 drug manufacture in 1Q:18. G&A expenses rose on greater stock compensation paid to the former CEO in lieu of cash compensation. Net loss was ($2.1) milion or ($0.10) per share, reflecting 20.4 million shares outstanding.

As of March 31, 2019, cash stood at $12.7 million and debt remained at zero. Cash burn was ($2.2) million for the quarter, compared to ($1.9) million in 1Q:18. A small amount was contributed from financing activities representing the exercise of pre-funded warrants. Phio management sees current cash levels as sufficient to fund the company until 2H:20.

**Dermatology and Ophthalmology Assets**

Phio continues to meet with potential acquirors and partners for RXI-109 and Samcyprone. The company is seeking a large dermatology player for the scarring indication and feedback has been limited. Potential buyers are seeking an advanced asset that can be approved within a short time period or a 505(b)(2) type of asset that is already understood by the regulatory agencies and RXI-109 for scarring is outside of this zone. We continue to see value here and anticipate that Phio will continue meeting with interested suitors until the environment shifts in their favor. Samcyprone can address an unmet need in warts and we think it can fill a niche in the retail space. The asset also can extend into other areas such as genital warts, precancerous lesions and has an orphan designation for skin cancer. No deals have yet been announced for this asset. Data for RXI-109 for retinal fibrosis and corneal scarring was the last to be fully available for review and could have the greatest near term value of the for-sale assets. In April, Regeneron and Alnylam announced a collaboration with $800 million in upfront cash to focus on disease targets expressed in the eye and central nervous system. This demonstrates that there is value recognized for RNAi in ophthalmology indications and we are hopeful that the value of Phio's asset will also be acknowledged. Despite the slow pace, we are optimistic that Phio will successfully monetize these partially developed assets.

**Poster Presentation**

On March 25, 2019, Phio presented a poster entitled "Feasibility and efficacy using self-delivering RNAi against TGFβ1 to reduce TME immunosuppression" at the American Association for Cancer Research (AACR) Annual Meeting. The poster and presentation highlighted the ability of sd-rxRNA to downregulate TGFβ1[2] and reduce immunosuppressive activity and promote T cell anti-tumor activity.

The study found that sd-rxRNA was efficiently taken up by cancer and immune cells in a mouse model of breast cancer. In the model, the sd-rx TGFβ1 demonstrated favorable distribution and target pathway downregulation.

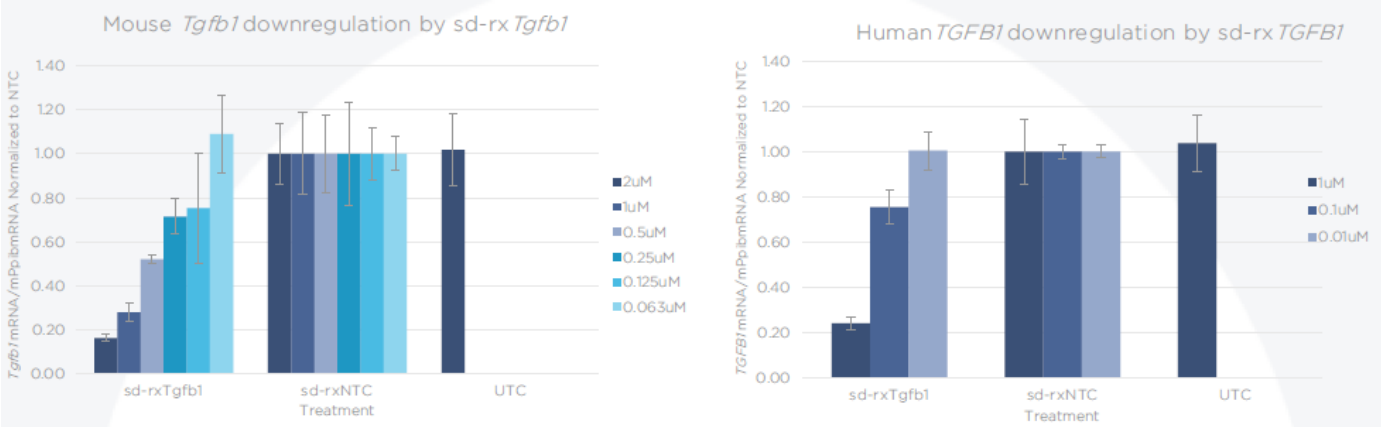
[1] In the May 2019 corporate presentation, product designations changed from RXI-762 to PH-762 and RXI-804 changed to PH-804 to reflect the new corporate name.

[2] Courtesy of Wikipedia: https://en.wikipedia.org/wiki/TGF_beta_1 Transforming growth factor beta 1 or TGF-β1 is a polypeptide member of the transforming growth factor beta superfamily of cytokines. It is a secreted protein that performs many cellular functions, including the control of cell growth, cell proliferation, cell differentiation, and apoptosis. In humans, TGF-β1 is encoded by the TGFB1 gene.

Futher conclusions from the study show that injections of sd-rx TGFβ1 can reduce the reduce immuno-suppression and boost immune effector cell activity. Work here paves the way for future clinical development activities in combination with adoptive cell therapy or other immuno-oncology efforts.

sd-rx TGFβ1 was incubated with breast cancer or NSCLC cells for 72 hours, and demonstrated a dose response of silencing gene expression as illustrated in the leftmost grouping in each of the two following panels. This *ex-vivo* model is supportive of favorably modulating the immunosuppressive tumor microenvironment to allow T cells to clear cancer cells.

**Exhibit I – Ex vivo Modulation of Tgfβ1 in Simulated Tumor Microenvironment**[3]




## Glycostem Collaboration

On March 28th, Phio announced a collaboration with Glycostem which will combine sd-rxRNA with Glycostem's oNKord cell therapy products. Glycostem is a Netherlands-based cell therapy company that has developed a platform technology employing *ex vivo* expansion of natural killer (NK) cells for use in immuno-oncology. The goal of the collaboration is to advance Glycostem's celular immunotherapies for the treatment of cancer. sd-rxRNA may provide new and effective methods for expanding and differentiating NK cells and address immunosuppressive environments that NK cells may encounter. Glycostem joins other Phio collaborators including CCIT, Medigene AG, Iovance Biotherapeutics and others.

## Patent Issued

On May 28, 2019, the United States Patent and Trademark Office (USPTO) issued patent number 10,300,027 entitled "Effective sensitizing dose of a gelled immunomodulating topical composition." The patent employs diphenylcyclopropenone (DPCP), otherwise known as Samcyprone, for which Phio has completed a Phase II trial for the indication of common warts. DPCP is an immunomodulator and can provoke an immune response, which has been studied in the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma. With this patent, Phio has broadened its intellectual property protections in skin cancer and melanoma. Company strategy seeks to protect work the company has done with licensed compounds in other than lead indications. While DPCP is not an active target for Phio, the patent will protect potential advances the company may make in the future.

[3] Mouse breast cancer 4T1 cells (left) or human non-small cell lung cancer A549 cells (right) were incubated with sd-rx-Tgfb1 targeting mouse Tgfb1, or sd-rx-Tgfb1 targeting human TGFB1, respectively in culture media containing 2% FBS. Seventy two hours after incubation, downregulation of Tgfb1 mRNA was evaluated by branched-DNA assay or RT-PCR.

**CEO Appointment and Management Changes**

As of March 1st, Gerrit Dispersyn was appointed chief executive officer (CEO). Dr. Dispersyn joined the company in April 2017 as Chief Development Officer and was promoted to President and Chief Operating Officer in 2018. He takes the reins from Dr. Geert Cauwenbergh, who will remain as member of Phio's board of directors.

On April 10, Phio appointed Dr. John Barrett as Chief Development Officer. Dr. Barrett's background at Ziopharm Oncology for the past eight years provided experience in drug discovery and in developing cell-based immuno-oncology therapies.

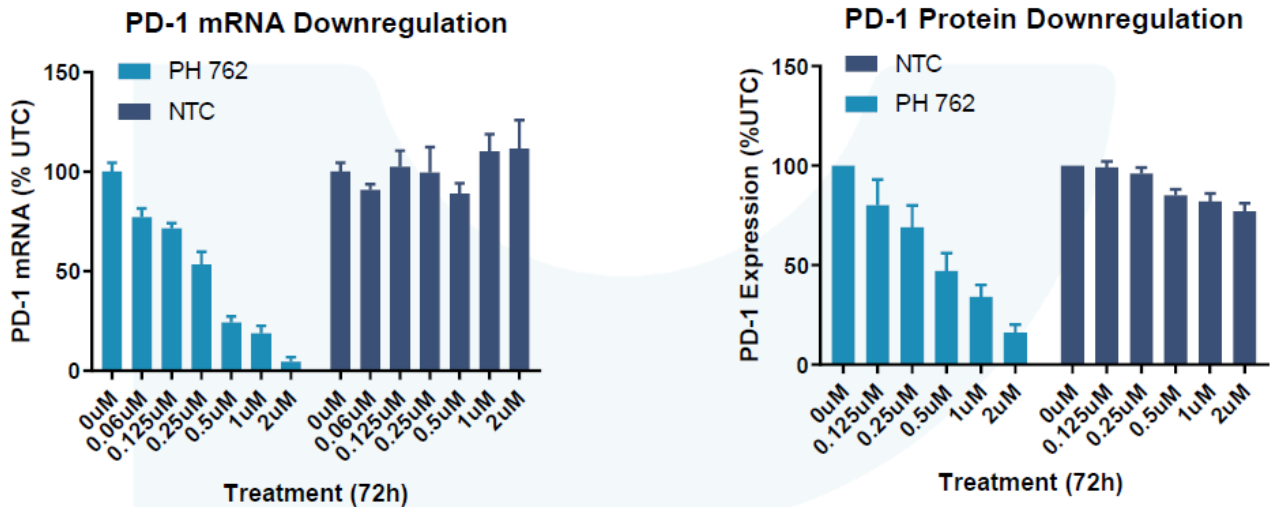
**Programs & Partnerships**

Phio maintains a relationship with the CCIT at Herlev Hospital to develop tumor-infiltrating lymphocytes (TILs) for cell therapies. Phio's sd-rxRNA is being used with TILs to modify their use in order to target immune checkpoints in cells from melanoma and other cancer patients. The use of sd-rxRNA with TILs has reduced the number of PD-1 receptors on the TILs' surface in a pilot study.

Phio is working with Iovance Biotherapeutics to develop and commercialize autologous cellular immunotherapies with tumor-directed TILs. Work with Iovance will combine sd-rxRNA with Iovance's autologous cell therapy approach in the treatment of cancer. In collaborative efforts, knock-down of PD-1 was associated with phenotypic changes suggesting TIL activation. Future efforts will evaluate the impact of sd-rxRNA on TIL activty.

The Medigene AG collaboration is combining sd-rxRNA with T cell receptors (TCR) to enhance the safety and efficiacy of their use in the treatment of cancer patients. Initial work with Medigene reduced PD-1 levels in T cells and the future goal is to expand to additional targets.

**Exhibit II – Dose Response for PD-1 Silencing Using PH-762[4]**




Combined efforts with Gustave Roussy employ sd-rxRNA in the tumor micro environment (TME). Intra-tumoral injection is applied to silence gene expression. Study results demonstrated an 80 – 85% reduction of the target gene expression in a melanoma mouse model.

[4] Exhibit compares the non-targeting control (NTC) with PH-762 at varying doses from 0 to 2 µM. The declining light blue bars illustrate the dose response in a reduction of PD-1 mRNA while the dark blue bars of the control are relatively steady.

## Pipeline Candidates

The following exhibit illustrates Phio's pipeline, which also includes undisclosed compounds in adoptive cell therapy (ACT) and tumor microenvironment. The lead asset is PH-762, which seeks to increase the expression of PD-1 in cell based therapies. Earlier stage programs are targeting the immune receptor TIGIT in solid tumors among other checkpoints. Cell differentiation is another program that is seeking to extend the life of modified immune cells so they will work longer.

**Exhibit III – Phio Pipeline**

| MECHANISM | INDICATION | DISCOVERY | PRECLINICAL | CLINICAL | COMMENT |
|---|---|---|---|---|---|
| Checkpoint Inhibition in ACT (TILs) | Melanoma (+ others) | PH-762 | | | Entering clinic 1H 2020 |
| Checkpoint Inhibition in TME (Direct - IT) | Melanoma (+ others) | PH-762 | | | Entering clinic 2H 2020 |
| Checkpoint Inhibition in ACT (T cells/NKs) | Various | PH-804 | | | Entering clinic 2H 2020 |
| Checkpoint Inhibition in TME (Direct - IT) | Various | PH-804 | | | |
| Checkpoint Inhibition in ACT (T cells/NKs) | Various | PD1/PD-L1 Axis | | | |
| Checkpoint Inhibition in TME (Direct - IT) | Various | PD1/PD-L1 Axis | | | |
| T cell exhaustion in ACT (T cells) | Various | Undisclosed | | | |
| Metabolism in ACT (T cells /NKs) | Various | Undisclosed | | | |
| Metabolism in TME (Tumor cells) | Various | Undisclosed | | | |
| Innate Immunity (NKs, DCs, Macrophages) | Various | Various | | | |

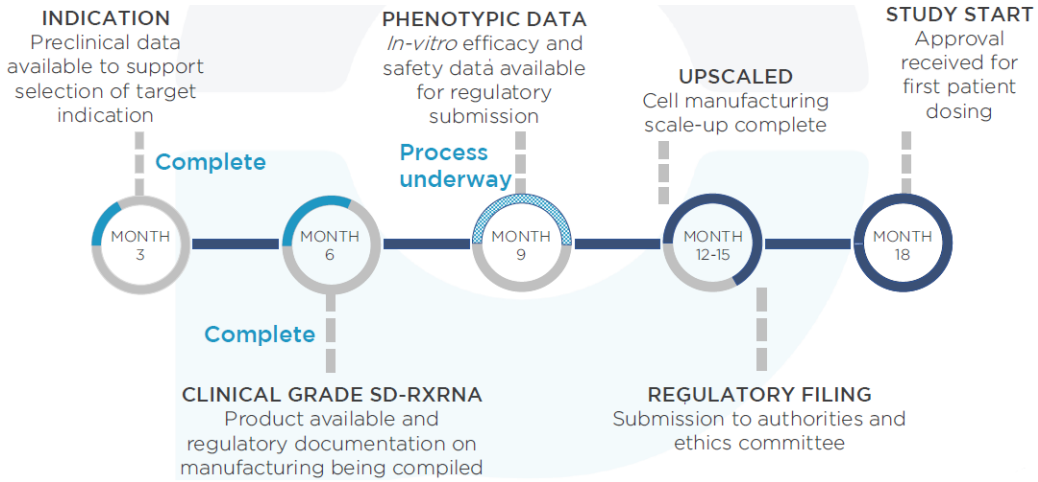
## NASDAQ Compliance

On November 2, 2018 Phio received a letter from NASDAQ stating that the company was not in compliance with exchange rules due to share price. The requirement calls for the minimum bid for shares to be $1.00, and falling below this level for thirty consecutive days violates the rule. The notification letter gave the company 180 days to achieve compliance, which is defined as 10 consecutive days of a minimum bid price of $1.00. The original compliance target date was May 14, 2019. In the 1Q:19 10-Q, Phio reported that the date was extended to November 11, 2019, providing an additional six months to achieve compliance. If the shares are delisted from the NASDAQ, Phio will likely trade on the OTC Bulletin Board or OTCQX market.

## Milestones:

- Addition of partner Glycostem for NK IO treatment development – March 2019
- Elevation of Dr. Gerrit Dispersyn to CEO – March 2019
- Appointment of Dr. John Barrett to CDO – April 2019
- Partnership/Sale of Dermatology and Ophthalmology Programs – TBD
- Preparation of IND for PH-762 – 2H:19
- New PD-1/PD-L1 product
- PH-762 (TILs – Melanoma) into clinic – 1H:20
- PH-762 (Intratumoral injection – Melanoma) into clinic – 2H:20
- PH-804 (ACT) into clinic – 2H:20

**Exhibit IV – Clinical Development Path PH-762[5]**




## 2021 Estimates

We introduce our 2021 estimates which reflect additional research and development spending for more advanced clinical trials following an anticipated successful Phase I effort. We also increase the share count to reflect additional capital raised to support the additional work. Our model and income statement at the end of the report provides numerical estimates.

## Summary

Phio remains in negotiations with potential buyers regarding the dermatology and ophthalmology assets. We are hopeful that execution on this sale will add to cash levels and be reflected in the valuation.[6] Phio has a multi-pronged approach to its immuno-oncology efforts, with three broad areas of research conducted in collaboration with partners. Immuno-oncology is an attractive area for development as the FDA frequently provides preferential consideration for candidates pursuing a cancer indication and there is broad demand for therapies in this pathology. Phio's sd-rxRNA has many favorable characteristics, including low cost, a high degree of safety, and the ability to enhance the IP of partner products to name a few. Phio has indicated that they have sufficient cash to support activity until 2H:20, a runway that may be extended with funds generated from asset sales. We maintain our target price at $2.00 per share.

[5] As of January 2019
[6] We discuss the Samcyprone and PHIO-109 in a previous report found here.
https://s1.q4cdn.com/460208960/files/News/2018/Zacks_SCR_Research_08202018_PHIOI_Vandermosten.pdf

## PROJECTED FINANCIALS

**Phio Pharmaceuticals Corp. - Income Statement**

| Phio Pharmaceuticals Corp | 2018 | Q1 A | Q2 E | Q3 E | Q4 E | 2019 E | 2020 E | 2021 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$0.1** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.0** |
| *YOY Growth* | | | | | | | | |
| Research & Development | $4.3 | $1.1 | $1.0 | $1.0 | $1.3 | $4.4 | $5.0 | $8.0 |
| General & Administrative | $3.2 | $1.1 | $0.9 | $1.0 | $1.0 | $4.0 | $4.0 | $4.5 |
| Income from operations | ($7.4) | ($2.1) | ($1.9) | ($2.0) | ($2.3) | ($8.3) | ($9.0) | ($12.5) |
| *Operating Margin* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Interest Income | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Other Income | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($7.4) | ($2.1) | ($1.9) | ($2.0) | ($2.3) | ($8.3) | ($9.0) | ($12.5) |
| Provision for Income Tax | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **Net Income** | **($7.4)** | **($2.1)** | **($1.9)** | **($2.0)** | **($2.3)** | **($8.3)** | **($9.0)** | **($12.5)** |
| | | | | | | | | |
| **Reported EPS** | **($1.80)** | **($0.10)** | **($0.08)** | **($0.08)** | **($0.09)** | **($0.36)** | **($0.35)** | **($0.25)** |
| *YOY Growth* | | | | | | | | |
| Basic Shares Outstanding | 7.04 | 20.42 | 23.90 | 24.00 | 24.30 | 23.15 | 26.00 | 50.00 |

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

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## HISTORICAL STOCK PRICE

**Phio Pharmaceuticals Corp. – Share Price Chart**



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