# Section 1: 8-K (FORM 8-K)

# 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): **March 16, 2018**

# Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-35366** | **20-5157386** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**2 Gansevoort Street, 9th Floor**
**New York, NY 10014**
(Address of Principal Executive Offices)

**(781) 652-4500**
(Registrant's telephone number, including area code)

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

☐ Written communications pursuant to Rule 425 under the Securities Act.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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. ☐

**Item 2.02. Results of Operations and Financial Condition.**

On March 16, 2018, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the year ended December 31, 2017. A copy of such press release is being furnished as Exhibit 99.1 to this report.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release issued by Fortress Biotech, Inc., dated March 16, 2018. |

**SIGNATURE**

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: March 16, 2018

**Fortress Biotech, Inc.**
(Registrant)

By /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer

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(Back To Top)

# Section 2: EX-99.1 (EXHIBIT 99.1)

**Exhibit 99.1**

## Fortress Biotech Reports Fourth Quarter and Full-Year 2017 Financial Results and Recent Corporate Highlights

**New York, NY – March 16, 2018** – Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2017.

Lindsay A. Rosenwald, M.D., Fortress Biotech's Chairman, President and Chief Executive Officer, said, "In 2017, we continued to build our portfolio of subsidiary companies, with the launch of Aevitas Therapeutics, Caelum Biosciences, Cyprium Therapeutics and Tamid Bio, strengthening our position in gene therapy and rare disease. In addition, our established Fortress Companies achieved several significant milestones, including the expansion of Mustang Bio's CAR T pipeline and a partnership with Harvard University and Beth Israel Deaconess Medical Center for the development of CRISPR/Cas9-enhanced CAR T therapies. In the third quarter of 2017, Mustang announced an exclusive, worldwide licensing agreement with the Fred Hutchinson Cancer Research Center for CD20-specific CAR T technology, which is currently in a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. Other significant milestones achieved by our Fortress Companies include an FDA RMAT designation for Cellvation's CEVA101 in severe traumatic brain injury, the dosing of a pivotal Phase 3 trial of Avenue Therapeutics' IV tramadol in postoperative pain and the Nasdaq listing of three Fortress Companies."

Dr. Rosenwald continued, "The year culminated with the presentation of clinical data on Caelum's CAEL-101 and Mustang's MB-102 in oral sessions at the American Society of Hematology Annual Meeting in December. In 2018, we look forward to building on the momentum of 2017, as we continue to advance promising therapies through clinical development and evaluate additional opportunities to fortify our portfolio."

**Financial Results:**

- As of December 31, 2017, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), cash deposits

with clearing organizations and restricted cash totaled $168.3 million, compared to $172.6 million as of September 30, 2017, and $105.2 million as of December 31, 2016, a decrease of $4.3 million for the fourth quarter and an increase of $63.1 million year-to-date.

- Net revenue totaled $187.6 million as of December 31, 2017, compared to $16.5 million as of December 31, 2016. Total revenue as of December 31, 2017 includes $17.2 million of Fortress revenue and $170.4 million of revenue from National Holdings Corporation ("National"). Total revenue as of December 31, 2016, includes $6.2 million of Fortress revenue and $10.3 million of revenue from National. No revenue is attributable to National prior to Fortress' acquisition of the company in September 2016.

- Research and development expenses were $48.3 million for the year ended December 31, 2017, of which $40.6 million was related to Fortress Companies. This compares to $29.6 million for 2016, of which $27.6 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in research and development were $4.0 million for the year ended December 31, 2017, compared to $4.7 million for 2016.
- Research and development expenses from license acquisitions totaled $4.2 million for the year ended December 31, 2017, compared to $5.5 million for 2016.
- General and administrative expenses were $50.9 million for the year ended December 31, 2017, of which $31.4 million was related to Fortress Companies. This compares to $34.0 million for 2016, of which $16.5 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $9.4 million for the year ended December 31, 2017 compared to $7.4 million for 2016.
- National's operating expenses totaled $181.8 million for the year ended December 31, 2017, compared to $12.3 million for 2016, with no expenses attributable to National prior to Fortress' acquisition of the company in September 2016.
- Net loss attributable to common stockholders was $66.9 million, or $1.61 per share, for the year ended December 31, 2017, compared to a net loss attributable to common stockholders of $55.1 million, or $1.38 per share, for 2016.

**2017 and Recent Fortress Biotech and Fortress Company Highlights:**

**Fortress Biotech, Inc.**

- In November 2017, Fortress closed an underwritten public offering of its 9.375 percent Series A Cumulative Redeemable Perpetual Preferred Stock at a price of $25.00 per share and received net proceeds totaling approximately $22.2 million.
- As of December 31, 2017, Fortress raised a total of $28.4 million in a subordinated note financing. National Securities Corporation, a subsidiary of National, acted as placement agent in connection with such financing.
- In 2017, Fortress launched four Fortress Companies: Caelum Biosciences, Inc., focused on treatments for amyloid light chain ("AL") amyloidosis; Cyprium Therapeutics, Inc., to develop novel therapies for the treatment of Menkes disease and related copper metabolism disorders; Aevitas Therapeutics, Inc., to develop novel gene therapy approaches for complement-mediated diseases; and Tamid Bio, Inc., to develop adeno-associated virus ("AAV") gene therapies in orphan diseases with unmet medical needs.

**Aevitas Therapeutics, Inc.**

- In February 2018, Aevitas entered into a sponsored research agreement with the laboratory of Guangping Gao, Ph.D., at the University of Massachusetts Medical School to evaluate construct optimization in the development of gene therapies based on Aevitas' AAV technology.

**Avenue Therapeutics, Inc.**

- In February 2017, the U.S. Patent and Trademark Office (USPTO) issued Avenue two continuation patents covering methods of administration for IV tramadol for the treatment of acute pain.
- In May 2017, Avenue announced a Notice of Allowance from the USPTO for a new patent application (U.S. Application No. 15/163,111) titled "Intravenous Administration of Tramadol." The patent application describes and claims a dosing regimen of IV 50 mg tramadol that provides certain pharmacokinetic parameters that are similar to those of 100 mg tramadol HCl administered orally every six hours at a steady state. The patent (U.S. Patent No. 9,693,949) was issued in July 2017.
- In June 2017, Avenue completed an initial public offering of 6,325,000 shares of common stock at a public offering price of $6.00 per share, resulting in net proceeds of $34.2 million. Avenue's common stock began trading on The NASDAQ Capital Market in June 2017 under the ticker symbol "ATXI."

- In September 2017, Avenue dosed the first patient in its pivotal Phase 3 trial of IV tramadol for the management of moderate to moderately severe postoperative pain in patients following bunionectomy surgery. Topline data are expected in the second quarter of 2018.
- In December 2017, Avenue dosed the first patient in the Phase 3 safety trial of IV tramadol for the management of moderate to moderately severe postoperative pain.

**Caelum Biosciences, Inc.**

- In January 2017, Caelum entered into an agreement with Columbia University ("Columbia") to secure exclusive, worldwide license rights to CAEL-101, a monoclonal antibody for the treatment of AL Amyloidosis.
- In April 2017, the U.S. Department of Health & Human Services confirmed the transfer of two U.S. Food and Drug Administration ("FDA") Orphan Drug Designations for CAEL-101 from Columbia to Caelum. The designations cover use of CAEL-101 as a therapeutic agent for patients with AL amyloidosis and as a radio-imaging agent in amyloidosis.
- In May 2017, Columbia dosed the final patient in the Phase 1b trial of CAEL-101 in AL amyloidosis.
- Also, in May 2017, Caelum entered into a biopharmaceutical manufacturing agreement with Patheon Biologics, LLC for process development and current good manufacturing practices ("cGMP") production to support Phase 2/3 studies of CAEL-101.
- In June 2017, Columbia filed a provisional patent application with the USPTO pertaining to CAEL-101 that will provide composition of matter protection effective upon a grant of a U.S. patent. In August 2017, Columbia filed a second provisional patent application for additional method of treatment claims directed to positive outcomes observed in the Phase 1b trial of CAEL-101.
- In the third quarter of 2017, Caelum raised $9.9 million in a third-party convertible note financing. National Securities Corporation, a subsidiary of National, acted as placement agent in connection with such financing.
- In December 2017, Columbia presented Phase 1a/1b data on CAEL-101 during an oral session at the 59th American Society of Hematology ("ASH") Annual Meeting. These data support CAEL-101's tolerability profile and potential to safely promote amyloid resolution.

**Cellvation, Inc.**

- In November 2017, Cellvation announced that the FDA granted CEVA101 (autologous bone marrow-derived stem cells) Regenerative Medicine Advanced Therapy ("RMAT") designation for the treatment of severe traumatic brain injury ("TBI"). Under terms of the RMAT designation, the FDA will help facilitate the expedited development and review of CEVA101 for severe TBI.

**Checkpoint Therapeutics, Inc.**

- In February 2017, the USPTO issued a composition of matter patent for CK-101, an oral, third-generation epidermal growth factor receptor ("EGFR") inhibitor in development for the treatment of EGFR mutation-positive non-small cell lung cancer ("NSCLC").
- In June 2017, Checkpoint's common stock began trading on The NASDAQ Capital Market under the ticker symbol "CKPT."
- In September 2017, Checkpoint announced that the FDA granted Orphan Drug Designation to CK-101 for the treatment of EGFR mutation-positive NSCLC.
- In October 2017, Checkpoint announced that the first patient had been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of CK-301, an anti-PD-L1 antibody, in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers.
- In March 2018, Checkpoint completed an underwritten public offering that raised net proceeds of $20.9 million.

**Cyprium Therapeutics, Inc.**

- In March 2017, Cyprium entered into a Cooperative Research and Development Agreement ("CRADA") with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"), for the advancement of Phase 3 candidate CUTX-101, a Copper Histidinate injection, for the treatment of Menkes disease and related copper metabolism disorders.
- Also, in March 2017, Cyprium and the NICHD entered into a worldwide, exclusive license agreement to develop and commercialize the AAV-based gene therapy AAV-ATP7A for use in combination with CUTX-101 in Menkes disease.

**Mustang Bio, Inc.**

- Mustang completed a private placement offering that raised aggregate gross proceeds totaling $95.1 million, $56.0 million of which was raised in 2017.
- In June 2017, Mustang announced exclusive, worldwide licensing agreements with City of Hope ("COH") for the use of three CAR T therapies in the development of cancer treatments: human epidermal growth factor receptor 2 CAR T technology ("HER2") for initial application in glioblastoma multiforme; CS1-specific CAR T technology ("CS1") to be directed against multiple myeloma; and prostate stem cell antigen CAR T technology ("PSCA") for the treatment of prostate, pancreatic, bladder and gastric cancers.
- In August 2017, Mustang's common stock commenced trading on The NASDAQ Global Market under the symbol "MBIO."
- In September 2017, Mustang announced an exclusive, worldwide licensing agreement with the Fred Hutchinson Cancer Research Center ("Fred Hutch") for CD20-specific CAR T technology ("CD20"). As part of the transaction, Mustang entered into an investigator-initiated clinical trial agreement to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. The trial began recruiting participants in the fourth quarter of 2017.
- In October 2017, Mustang announced that COH received a $12.8 million grant from the California Institute for Regenerative Medicine to fund an ongoing Phase 1 study of Mustang's MB-101 (IL13Rα2-specific CAR T cells) for the treatment of patients with recurrent and refractory malignant glioma, including glioblastoma.
- Also, in October 2017, Mustang entered into a lease agreement with the UMass Medicine Science Park in Worcester, Massachusetts, for a cell processing facility to support the clinical development and commercialization of Mustang's CAR T product candidates. The facility is expected to be operational in 2018.
- In December 2017, Mustang entered into a license agreement with Harvard University and a sponsored research agreement with Beth Israel Deaconess Medical Center for the development of CRISPR/Cas9-enhanced CAR T therapies for the treatment of cancer.
- In December 2017, COH presented initial data from an ongoing Phase 1 clinical trial of MB-102 (CD123 CAR) in acute myeloid leukemia ("AML") and blastic plasmacytoid dendritic cell neoplasm ("BPDCN") during an oral session at the American Society of Hematology Annual Meeting. These data demonstrated that MB-102 achieved the first complete response from a CAR T therapy in a BPDCN patient, with an additional complete response in AML.

**Tamid Bio, Inc.**

- In November 2017, Tamid entered into three exclusive licensing agreements with the University of North Carolina at Chapel Hill for three preclinical AAV gene therapies to be applied in orphan diseases with unmet medical needs. Tamid's lead program, Tamid-001, targets the ocular manifestations of Mucopolysaccharidosis type I ("MPS I"), a rare and progressively debilitating disorder, caused by mutations in the IDUA gene, leading to the accumulation of glycosaminoglycans ("GAGS") in multiple organs. Tamid also in-licensed two earlier-stage assets, which will target dysferlinopathies and corneal transplant rejection.

**About Fortress Biotech**
Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.com.

**Forward-Looking Statements**
This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law.

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**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Consolidated Balance Sheets**
**($ in thousands except for share and per share amounts)**

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 113,915 | $ 88,294 |
| Accounts receivable | 7,758 | 1,830 |
| Short-term investments (certificates of deposit) | 36,002 | - |
| Cash deposits with clearing organizations | 1,041 | 1,030 |
| Receivables from broker-dealers and clearing organizations | 7,395 | 3,357 |
| Forgivable loans receivable | 1,616 | 1,712 |
| Securities owned, at fair value | 1,985 | 2,357 |
| Inventory | 171 | 203 |
| Other receivables - related party | 618 | 1,790 |
| Prepaid expenses and other current assets | 12,680 | 9,061 |
| Total current assets | 183,181 | 109,634 |
| | | |
| Property and equipment, net | 9,513 | 7,376 |
| Restricted cash | 17,387 | 15,860 |
| Long-term investments, at fair value | 1,390 | 1,414 |
| Intangible assets | 15,223 | 17,408 |
| Goodwill | 18,645 | 18,645 |
| Other assets | 611 | 394 |
| **Total assets** | **$ 245,950** | **$ 170,731** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 36,127 | $ 24,295 |
| Accounts payable and accrued expenses – related party | 222 | - |
| Accrued commissions and payroll payable | 10,065 | 11,940 |
| Deferred clearing and marketing credits | 786 | 995 |
| Securities sold, not yet purchased, at fair value | 151 | 298 |
| Warrants issued in 2017 and issuable in 2016 - National | 5,597 | 14,359 |
| Interest payable | 315 | 88 |
| Interest payable - related party | 669 | 77 |
| Notes payable, short-term (net of debt discount of $973 and $0 at December 31, 2017 and December 31, 2016, respectively) | 8,528 | 1,000 |
| Subsidiary convertible note, short-term, at fair value | 4,700 | 1,031 |
| Contingently issuable liabilities | - | 1,682 |
| Derivative warrant liability | 87 | 481 |
| Other current liabilities | 181 | 319 |
| Total current liabilities | 67,428 | 56,565 |
| | | |
| Notes payable, long-term (net of debt discount of $62 and $2,009 at December 31, 2017 and December 31, 2016, respectively) | 43,222 | 22,528 |
| Subsidiary convertible note, long-term, at fair value | 10,059 | 3,656 |
| Other long-term liabilities | 4,739 | 5,014 |
| **Total liabilities** | **125,448** | **87,763** |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Stockholders' equity** | | |
| Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares 1,000,000 and 0 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively | 1 | - |
| | | |
| Common Stock, $.001 par value, 100,000,000 shares authorized, 50,991,285 and 48,932,023 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively | 51 | 49 |
| Common stock issuable, 158,015 and 0 shares as of December 31, 2017 and December 31, 2016, respectively | 500 | - |
| Additional paid-in-capital | 364,148 | 283,697 |
| Accumulated deficit | (312,127) | (245,251) |
| Total stockholders' equity attributed to the Company | 52,573 | 38,495 |
| | | |

| | | |
|---|---|---|
| Non-controlling interests | 67,929 | 44,473 |
| Total stockholders' equity | 120,502 | 82,968 |
| **Total liabilities and stockholders' equity** | **$ 245,950** | **$ 170,731** |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Consolidated Statement of Operations**
**($ in thousands except for share and per share amounts)**

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | **2017** | **2016** | **2015** |
| **Revenue** | | | |
| ***Fortress*** | | | |
| Product revenue, net | $ 15,520 | $ 3,587 | $ 273 |
| Revenue - from a related party | 1,725 | 2,570 | 590 |
| Net Fortress revenue | 17,245 | 6,157 | 863 |
| | | | |
| ***National*** | | | |
| Commissions | 96,807 | 5,388 | - |
| Net dealer inventory gains | 15,108 | 253 | - |
| Investment banking | 25,064 | 2,829 | - |
| Investment advisory | 14,528 | 904 | - |
| Interest and dividends | 2,764 | 155 | - |
| Transfer fees and clearing services | 7,393 | 386 | - |
| Tax preparation and accounting | 7,439 | 338 | - |
| Other | 1,236 | 70 | - |
| Total National revenue | 170,339 | 10,323 | - |
| Net revenue | 187,584 | 16,480 | 863 |
| | | | |
| **Operating expenses** | | | |
| ***Fortress*** | | | |
| Cost of goods sold – product revenue | 3,658 | 790 | - |
| Research and development | 48,322 | 29,602 | 18,402 |
| Research and development – licenses acquired | 4,164 | 5,532 | 11,408 |
| General and administrative | 50,897 | 34,003 | 21,584 |
| Total Fortress operating expenses | 107,041 | 69,927 | 51,394 |
| | | | |
| ***National*** | | | |
| Commissions, compensation and fees | 155,187 | 10,414 | - |
| Clearing fees | 2,343 | 144 | - |
| Communications | 2,767 | 177 | - |
| Occupancy | 4,286 | 193 | - |
| Licenses and registration | 1,726 | 147 | - |
| Professional fees | 4,531 | 327 | - |
| Interest | 14 | 1 | - |
| Depreciation and amortization | 2,089 | 545 | - |
| Other administrative expenses | 8,808 | 315 | - |
| Total National operating expenses | 181,751 | 12,263 | - |
| Total operating expenses | 288,792 | 82,190 | 51,394 |
| Loss from operations | (101,208) | (65,710) | (50,531) |
| | | | |
| Other income (expenses) | | | |
| Interest income | 819 | 298 | 245 |
| Interest expense and financing fee | (5,860) | (3,690) | (1,484) |
| Change in fair value of derivative liabilities | 8,391 | (1,039) | (438) |
| Change in fair value of subsidiary convertible note | (457) | (78) | - |
| Change in fair value of investments | 226 | (1,071) | (1,675) |
| Other loss | (234) | - | - |
| Total other income (expenses) | 2,885 | (5,580) | (3,352) |
| Loss before income taxes | (98,323) | (71,290) | (53,883) |
| | | | |
| Income tax expense | 1,513 | - | - |
| **Net Loss** | **(99,836)** | **(71,290)** | **(53,883)** |
| Less: net loss attributable to non-controlling interests | 32,960 | 16,195 | 5,455 |
| **Net loss attributable to common stockholders** | **$ (66,876)** | **$ (55,095)** | **$ (48,428)** |
| | | | |
| Basic and diluted net loss per common share | $ (1.61) | $ (1.38) | $ (1.24) |
| | | | |
| Weighted average common shares outstanding—basic and diluted | 41,658,733 | 39,962,657 | 39,146,589 |

(Back To Top)