



## Ocular Therapeutix™ Reports Second Quarter 2025 Financial Results and Business Highlights

August 5, 2025

*Outstanding patient retention and clinical execution in complementary AXPAXLI™ SOL trials for wet AMD*

*SOL-1 remains on track for 1Q 2026 topline data*

*SOL-R rescue criteria streamlined and simplified with topline data expected in 1H 2027*

*Planning to incorporate single long-term extension study for both SOL trials*

*Ocular to host Investor Day on Tuesday, September 30, 2025, in New York City*

*Raised gross proceeds of approximately \$97 million in June 2025 through existing ATM facility*

*Cash balance of \$391.1 million as of June 30, 2025, with expected runway into 2028, well beyond anticipated topline data for SOL-1 and SOL-R*

BEDFORD, Mass., Aug. 05, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today reported financial results for the second quarter ended June 30, 2025, and provided recent business highlights.

"We are entering the most important phase of Ocular Therapeutix's history, marked by consistent execution, growing clinical conviction, and a clear roadmap to redefine the retina treatment landscape," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix. "With SOL-1 on track for topline data in the first quarter of 2026, followed by SOL-R topline data in the first half of 2027, we are building what we expect to be a powerful and highly differentiated clinical profile for AXPAXLI. Due to our increasing confidence and conviction in AXPAXLI's potential, we are now planning a long-term, open-label extension study for patients completing either of the SOL trials, and we are advancing SOL-R with streamlined and simplified rescue criteria that better reflect real-world practice. SOL-1 and SOL-R are thoughtfully crafted, complementary trials with bespoke patient populations designed to de-risk outcomes and answer key questions physicians will have on the durability, flexibility, and repeatability of AXPAXLI. As a result of this clinical strategy, AXPAXLI has the potential to secure an unprecedented superiority label in wet AMD. Recently approved anti-VEGF products and current competitive Phase 3 wet AMD trials are all based on non-inferiority to aflibercept (2 mg). To our knowledge, SOL-1 is the only Phase 3 superiority trial being conducted in wet AMD, and if we are successful in gaining FDA approval, we will potentially be the only product with a superiority claim in the label for the foreseeable future. We further expect the SOL program to enable dosing every 6 months to as infrequently as every 12 months. We believe this dynamic will allow us a unique and potentially dominant position compared to all other products in the commercial landscape, and could unlock an opportunity that spans millions of patients worldwide – addressing the critical needs for a more sustainable, less burdensome treatment, with potentially improved long-term outcomes."

**Dr. Dugel** continued, "Beyond wet AMD, we are thrilled with the FDA feedback supporting our NPDR and DME program, and we look forward to sharing more details at our Investor Day in September, along with the global commercial outlook for AXPAXLI and more. Our refreshed corporate branding, launched in June, reflects the Company we've become: retina-focused, patient-driven, and boldly advancing a potential new standard-of-care in retinal disease."

### Recent Achievements and Upcoming Milestones:

- **SOL-1 (Phase 3, wet AMD) retention and protocol adherence continues to be exceptional as topline data remains on track for 1Q 2026.** Patient engagement and investigator adherence to the study rescue protocol continue to be outstanding in the SOL-1 superiority study. Ocular plans to continue to follow patients completing the trial through a long-term extension study.
- **SOL-R (Phase 3, wet AMD) rescue criteria streamlined and simplified with topline data expected in 1H 2027.** The SOL-R non-inferiority study is the largest tyrosine kinase inhibitor (TKI) trial to date in retina. Based on investigator feedback, and as part of its ongoing effort to ensure SOL-R reflects real-world clinical decision-making, Ocular has streamlined and simplified the rescue criteria to a >5-letter loss in visual acuity plus a ≥75-micron increase in central subfield thickness (CSFT). This change aligns the trial more closely with how physicians determine when to intervene in the real world in the most conservative manner. This change was not an FDA requirement, but rather a strategic decision to further bridge the gap between clinical trial design and clinical practice. SOL-R remains robustly powered at 90% with the non-inferiority margin of -4.5 ETDRS letters per FDA guidance. SOL-R has completed enrollment and, based on its

projected randomization timeline, Ocular expects to report topline data in 1H 2027.

- **New Drug Application (NDA) filing for FDA review planned for shortly after topline results in SOL-R.** Because axitinib is FDA-approved for non-ophthalmic indications, the Company plans to leverage the 505(b)(2) NDA review pathway which has the potential to shorten the review timeline for AXPAXLI by two months compared to the traditional review pathway for new molecular entities. The FDA has previously communicated that SOL-1 and SOL-R should be appropriate for use as adequate and well-controlled studies to support a potential NDA and product label for wet AMD. If approved, Ocular believes AXPAXLI has the potential to be the first product for wet AMD with a superiority label based on the SOL-1 trial, with redosing potentially as infrequently as every 12 months.
- **The Company plans to incorporate a single long-term, open-label extension study for both SOL trials.** Subjects will be eligible to enter the extension study after completing the two-year safety follow-up period in either SOL-1 or SOL-R. In addition to providing long-term safety data, the study is expected to further inform the AXPAXLI treatment paradigm and potentially provide several commercial advantages. The extension study is designed to evaluate long-term safety and explore key efficacy outcomes such as vision preservation, anti-fibrotic activity, and the potential consequences of delaying AXPAXLI treatment in control arm patients.
- **Written feedback received from FDA on registrational trial in non-proliferative diabetic retinopathy (NPDR) for AXPAXLI.** Building on FDA's positive feedback received earlier this year, Ocular is actively engaged in defining its clinical strategy for AXPAXLI in NPDR and diabetic macular edema (DME). The Company plans to provide more details surrounding its clinical trial strategy and design at its upcoming Investor Day on September 30, 2025.
- **Opportunistically raised gross proceeds of approximately \$97 million in June 2025 through existing at-the-market (ATM) facility.** This additional capital provides Ocular with financial flexibility as the Company prepares for data from its first registrational trial in wet AMD, SOL-1, in the first quarter of 2026. Ocular remains well-financed with expected runway well beyond the anticipated receipt of SOL-1 and SOL-R topline data and into 2028.
- **Investor Day to be held the afternoon of Tuesday, September 30, 2025, in New York City.** The event will feature prominent retinal disease Key Opinion Leaders (KOLs) and presentations from senior Company leadership. Key areas of focus include: an overview of the complementary SOL trials and how they may support a differentiated superiority label for AXPAXLI in wet AMD; new details on the planned SOL extension study; the clinical strategy for NPDR and DME informed by recent FDA feedback; and a review of the global commercial opportunity for AXPAXLI across retinal indications. Additional event logistics and webinar information will be provided in advance. To register for Ocular's Investor Day, please visit Ocular's website or register [HERE](#).
- **Unveiled new corporate branding in June 2025 reflecting Ocular's transformation to a retina-focused company.** Ocular aims to redefine the retina experience by reducing the treatment burden and providing an alternative to the pulsatile nature of available treatments, in hopes of preserving vision for the long-term. The Company's new branding reflects Ocular's meaningful progress, driven by the momentum of its SOL trials and its commitment to patients.

## Second Quarter Ended June 30, 2025, Financial Results:

**Total cash and cash equivalents** were \$391.1 million as of June 30, 2025. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA<sup>®</sup>, the Company believes that its current cash balance is sufficient to support its planned expenses, debt service obligations, and capital expenditure requirements into 2028. This cash projection does not yet factor in the full impact of potential clinical trial activities for AXPAXLI in NPDR and DME or the long-term extension study in wet AMD, as Ocular is currently in the planning phases for these programs.

**Total net revenue** was \$13.5 million for the second quarter of 2025, an 18.1% decrease as compared to total net revenue of \$16.4 million in the comparable quarter in 2024. Total net revenue includes both gross DEXTENZA product revenue, net of discounts, rebates, and returns, which the Company refers to as net product revenue, and collaboration revenue.

DEXTENZA end-user unit sales were up 5% compared to the second quarter in 2024, however the reduction in net revenue was due to an evolving and significantly more challenging reimbursement environment for DEXTENZA in 2025. Strong execution by the Ocular commercial team has ensured the demand for DEXTENZA continues to grow, as evidenced by sustained unit growth. Compared to the first quarter of 2025, DEXTENZA net product revenue increased by 26.0% in the second quarter of 2025.

**Research and development expenses** for the second quarter of 2025 were \$51.1 million versus \$28.9 million for the comparable quarter in 2024, reflecting an increase in overall clinical expenses associated with the SOL-1 and SOL-R Phase 3 clinical trials, as well as additional personnel and professional services to support these clinical trials.

**Selling and marketing expenses** were \$13.7 million for the second quarter of 2025, as compared to \$10.0 million for the comparable quarter of 2024, primarily reflecting an increase in personnel-related costs, including stock-based compensation expense, and professional fees associated with pre-commercialization activities for AXPAXLI.

**General and administrative expenses** were \$14.3 million for the second quarter of 2025, as compared to \$19.7 million for the

comparable quarter of 2024, primarily due to a decrease in personnel-related costs, including stock-based compensation expense. The second quarter of 2024 includes one-time personnel-related costs, including stock-based compensation expense, for certain employees who departed the Company, and restructuring costs.

**Net loss for the second quarter of 2025** was \$(67.8) million, or a net loss of \$(0.39) per share on both a basic and diluted basis, compared to a net loss of \$(43.8) million, or a net loss of \$(0.26) per share on a basic and diluted basis, for the comparable quarter of 2024. The net loss in the second quarter of 2025 includes a net loss from the change in fair value of our derivative liability of \$(0.6) million, which is comprised of a non-cash loss from fair value measurement of the derivative liability associated with the Barings Credit Facility of \$(0.2) million, and expense related to actual royalty fees under the Barings Credit Facility of \$(0.5) million, compared to a \$(3.0) million net loss for the second quarter of 2024, which is comprised of a net non-cash loss attributable to fair value measurements of the derivative liabilities associated with the Barings Credit Facility and the Company's convertible notes of \$(2.5) million, and expense related to actual royalty fees under the Barings Credit Facility of \$(0.6) million.

**Outstanding shares** as of August 1, 2025, were approximately 174.0 million.

#### **Conference Call and Webcast Information:**

Ocular Therapeutix will host a conference call and webcast on Tuesday, August 5, 2025, at 8:00 AM ET to discuss recent business progress and financial results for the second quarter ended June 30, 2025. To access the call, please dial: 1-877-407-9039 (U.S.) or 1-201-689-8470 (International). The live and archived webcast can also be accessed by visiting the Ocular Therapeutix website on the Events and Presentations section of the Investor Relations page. A replay of the webcast will be archived for at least 30 days.

#### **About AXPAXLI**

AXPAXLI™ (also known as OTX-TKI) is an investigational, bioresorbable, intravitreal hydrogel incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD, diabetic retinopathy, diabetic macular edema, and other retinal diseases.

#### **About the SOL-1 Study**

The registrational Phase 3 SOL-1 trial (NCT06223958) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye.

The superiority study has an eight-week loading segment prior to randomization. During the loading segment, subjects who have 20/80 vision or better and who satisfy other enrollment criteria receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Eligible subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 or gain at least 10 early treatment diabetic retinopathy study (ETDRS) letters at Day 1 are then randomized to receive a single dose of AXPAXLI or a single dose of aflibercept (2 mg). At Week 52 and at Week 76, all subjects are re-dosed with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. The clinical trial protocol requires that, during the study, subjects in either arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, defined as a loss of <15 ETDRS letters of BCVA, at Week 36. Subjects will continue to be evaluated for durability up to Week 52. The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

#### **About the SOL-R Study**

The registrational Phase 3 SOL-R trial (NCT06495918) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (2:2:1), three-arm study that includes sites located in the U.S., Argentina, India, and Australia. The trial is intended to randomize approximately 555 subjects who are treatment-naïve or were diagnosed with wet AMD in the study eye within about four months prior to enrollment.

This non-inferiority trial reflects a patient enrichment strategy over the six months prior to randomization that includes three screening doses of any anti-VEGF therapy, excluding brolicizumab-dblb, and monitoring to exclude those subjects with significant retinal fluid fluctuations. Subjects that continue to meet eligibility will enter a run-in period and receive two loading doses of aflibercept (2 mg) prior to Day 1. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Weeks 24, 48, and 72. Subjects in the second arm receive aflibercept (2 mg) on-label every eight weeks. Subjects in the third arm receive a single dose of aflibercept (8 mg) at Day 1 and are re-dosed at Weeks 24, 48, and 72, aligned with the AXPAXLI treatment arm for adequate masking. Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. Subjects in any arm that meet pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg). The pre-specified rescue criteria include a >5-letter loss in visual acuity plus a ≥75-micron increase in central subfield thickness (CSFT).

The primary endpoint of SOL-R is to demonstrate non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at Week 56. As per the protocol agreed to by the FDA, the non-inferiority margin for the lower bound is -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every eight weeks. In a written Type C response

received in August 2024, and a subsequent written response received in December 2024, the FDA agreed that the SOL-R repeat dosing wet AMD study, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled study in support of a potential New Drug Application and product label for wet AMD.

### **About Wet AMD**

Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14.5 million individuals globally and 1.8 million in the United States alone (2024 Market Scope<sup>®</sup> Retinal Pharmaceuticals Market Report). Wet AMD causes vision loss due to abnormal new blood vessel growth and hyperpermeability and associated retinal vascularity in the macula, which is primarily stimulated by local upregulation of vascular endothelial growth factor (VEGF). Without prompt and continuous treatment to control this exudative activity, patients develop irreversible vision loss. With proper treatment, patients may maintain visual function for a period of time and may temporarily regain lost vision. Challenges with current therapies include pulsatile, repeated intraocular injections, treatment-related adverse events and up to 40% patient discontinuation within one year of initiating treatment with continued disease progression. Taken together, these factors lead to undertreatment and a lack of long-term vision improvement for patients.

### **About Ocular Therapeutix, Inc.**

Ocular Therapeutix, Inc. is an integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI<sup>™</sup> (also known as OTX-TKI), Ocular's investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based on its ELUTYX<sup>™</sup> proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in Phase 3 clinical trials for wet age-related macular degeneration (wet AMD).

Ocular's pipeline also leverages the ELUTYX technology in its commercial product DEXTENZA<sup>®</sup>, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in its investigational product candidate OTX-TIC, which is a travoprost intracameral hydrogel that is currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Explore the new corporate branding and follow the Company on its website, LinkedIn, or X.

DEXTENZA<sup>®</sup> is a registered trademark of Ocular Therapeutix, Inc. The Ocular Therapeutix logo, AXPAXLI<sup>™</sup>, ELUTYX<sup>™</sup>, and Ocular Therapeutix<sup>™</sup> are trademarks of Ocular Therapeutix, Inc.

### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA; the development, regulatory status of and regulatory submissions regarding the Company's product candidates; the design and conduct of, and the timing of the screening, enrollment and randomization of patients in and the availability of data from the Company's SOL-1 and SOL-R Phase 3 clinical trials of AXPAXLI (also known as OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI, including in additional indications such as NPDR and DME and in the Company's planned long-term extension study, and its plans to advance other product candidates; the potential utility or adoption, if approved, of any of the Company's product candidates; the Company's cash runway and the sufficiency of the Company's cash resources; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under the Special Protocol Assessment for the SOL-1 trial; the risk that the FDA may not agree that the protocol and statistical analysis plan of SOL-R or that the data generated by the SOL-1 and SOL-R trials support marketing approval, even if the trials are successful; the risk that the Company and the FDA may not agree on the registrational pathway for any of its product candidates; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials, whether preliminary or interim data from a clinical trial (including masked safety or masked rescue data from the Company's SOL-1 trial) will be predictive of final data from such trial, or whether data from a clinical trial assessing a product candidate for one indication will be predictive of results in other indications; uncertainty as to whether data from the Company's planned long-term, open-label extension study in wet AMD will demonstrate clinically meaningful, long-term benefits; uncertainties regarding the potential commercial advantages and/or position of the Company's product candidates; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; the Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The

Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

#### Investors & Media

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**Ocular Therapeutix, Inc.**  
**Consolidated Balance Sheets**  
 (in thousands, except share and per share data)

	June 30, 2025	December 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 391,134	\$ 392,102
Accounts receivable, net	30,412	32,388
Inventory	3,039	3,040
Prepaid expenses and other current assets	8,790	13,457
Total current assets	433,375	440,987
Property and equipment, net	10,461	9,389
Restricted cash	1,614	1,614
Operating lease assets	5,883	5,945
Total assets	<u>\$ 451,333</u>	<u>\$ 457,935</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,889	\$ 4,176
Accrued expenses and other current liabilities	34,417	35,117
Deferred revenue	—	128
Operating lease liabilities	2,625	1,933
Total current liabilities	42,931	41,354
Other liabilities:		
Operating lease liabilities, net of current portion	4,408	5,345
Derivative liability	14,024	13,246
Deferred revenue, net of current portion	14,000	14,000
Notes payable, net	69,906	68,505
Other non-current liabilities	148	141
Total liabilities	145,417	142,591
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at June 30, 2025 and December 31, 2024, respectively	—	—
Common stock, \$0.0001 par value; 400,000,000 shares and 400,000,000 shares authorized and 172,925,389 and 157,749,490 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	17	16
Additional paid-in capital	1,328,850	1,206,412
Accumulated deficit	(1,022,951)	(891,084)
Total stockholders' equity	305,916	315,344
Total liabilities and stockholders' equity	<u>\$ 451,333</u>	<u>\$ 457,935</u>

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	\$ 13,395	\$ 16,379	\$ 24,028	\$ 31,094
Collaboration revenue	64	62	128	121
Total revenue, net	<u>13,459</u>	<u>16,441</u>	<u>24,156</u>	<u>31,215</u>
Costs and operating expenses:				
Cost of product revenue	1,944	1,509	3,206	2,835
Research and development	51,081	28,857	93,938	49,592
Selling and marketing	13,729	9,994	27,877	20,177
General and administrative	14,346	19,671	30,694	33,818
Total costs and operating expenses	<u>81,100</u>	<u>60,031</u>	<u>155,715</u>	<u>106,422</u>
Loss from operations	<u>(67,641)</u>	<u>(43,590)</u>	<u>(131,559)</u>	<u>(75,207)</u>
Other income (expense):				
Interest income	3,455	6,036	7,282	9,958
Interest expense	(3,016)	(3,196)	(6,000)	(7,247)
Change in fair value of derivative liabilities	(641)	(3,027)	(1,619)	(8,179)
Loss on extinguishment of debt	—	—	—	(27,950)
Gain on sale of property and equipment	29	—	29	—
Total other expense, net	<u>(173)</u>	<u>(187)</u>	<u>(308)</u>	<u>(33,418)</u>
Net loss	<u>\$ (67,814)</u>	<u>\$ (43,777)</u>	<u>\$ (131,867)</u>	<u>\$ (108,625)</u>
Net loss per share, basic	<u>\$ (0.39)</u>	<u>\$ (0.26)</u>	<u>\$ (0.77)</u>	<u>\$ (0.73)</u>
Weighted average common shares outstanding, basic	<u>172,594,662</u>	<u>165,824,778</u>	<u>171,004,629</u>	<u>148,922,937</u>
Net loss per share, diluted	<u>\$ (0.39)</u>	<u>\$ (0.26)</u>	<u>\$ (0.77)</u>	<u>\$ (0.73)</u>
Weighted average common shares outstanding, diluted	<u>172,594,662</u>	<u>165,824,778</u>	<u>171,004,629</u>	<u>148,922,937</u>